# NCCCP-Developed Tools and Resources


NCI COMMUNITY CANCER CENTERS PROGRAM

2007–2014

*The resources developed by the NCCCP were used by participants to guide, assess, and measure cancer program activities related to the NCCCP's overarching objectives for the community-based setting: enhance access to care; improve the quality of care; and expand research initiatives. While not validated tools, they may be useful templates for other community cancer centers.*

# Contents

# NCCCP Disparities Vision Dashboard

This tool provides an overview of the program's efforts to address cancer healthcare disparities. The document specifies metrics used to ensure that disparities issues are considered in clinical trials, biospecimens, information technology, quality of care, and survivorship. The dashboard also outlines focused efforts around screening, community outreach, navigation, and tracking race and ethnicity data.

## NCCCP Disparities Vision Dashboard

The NCI, through public/private partnerships with NCCCP site community hospital-based cancer centers, will expand state-of-the-art cancer care and research to populations experiencing healthcare disparities (those with an excess burden from cancer) across the continuum, from prevention and screening through treatment, follow-up and end of life care.

### Definition of Disparities

Health Disparities: "Different public and private agencies have different definitions of a 'health disparity' for their own program-related purposes; however, these definitions tend to have several commonalities. In general, health disparities are defined as significant differences between one population and another. The Minority Health and Health Disparities Research and Education Act of 2000, which authorizes several HHS programs, describes these disparities as differences in "the overall rate of disease incidence, prevalence, morbidity, mortality or survival rates." The Institute of Medicine publication, "Unequal Treatment" highlights inequities related to access and treatment as major factors in defining disparities.

For the NCCCP, we define the populations affected by health disparities to include racial and ethnic minorities, and other underserved populations: residents of rural areas, women, children, the elderly, persons with disabilities, the uninsured, underinsured and those who are socioeconomically disadvantaged.

### NCCCP Disparities Dashboard

| Overall Disparities requirement |
|---|
| All patients screened and diagnosed with cancer by sites are offered treatment—policies in place with annual confirmation |
| All sites required to implement race and ethnicity tracking using OMB categories |
| **Cross-cutting priority initiatives** |
| Support underserved accrual to clinical trials |
| Support improved coordination between outreach, treatment, and survivorship navigation with a focus on underserved populations |
| Explore participation/collaboration in disparities research |

**Consolidated disparities metrics from sites by area of focus (OMB categories to be used for race and ethnicity metrics unless otherwise noted)**

| | Biospecimens | Quality of Care | Survivorship | Disparities |
|---|---|---|---|---|
| ■ % change underserved patient accrual<br>■ % attendance on underserved accrual working group calls | ■ % sites with policies for special handling of specimens for specific populations (e.g., Native Americans) | ■ CoC RQRS performance metrics using OMB categories<br>■ PROSSES Research Study using OMB categories/rural | ■ % of sites that offer Survivorship Care Plans in a language other than English<br>■ % of patients who do not receive Survivorship Care Plans (by race, ethnicity, & insurance status | ■ % change # of partnerships focused on underserved<br>■ % change # of screening events<br>■ % change # of patients screened for cancer<br>■ % change # patients navigated |

**Key Disparities Activities/Projects**

| Clinical Trials | Biospecimens | Quality of Care | Survivorship | Disparities |
|---|---|---|---|---|
| ■ Improve participation in underserved accrual working group<br>■ Improve navigation referrals to CT team | ■ Adopt biospecimen handling policies to address cultural and religious considerations<br>■ Increase culturally-appropriate community/ patient education on tissue donation | ■ Use RQRS data on underserved for program improvement<br>■ PROSSES Research Study to recruit racial & ethnic minority & rural patients | ■ Ensure that survivorship care plans are communicated to patients completing treatment for at least one clinic/disease site setting | ■ Identify barriers to care coordination for underserved patients<br>■ Improve quality of disparities data collection<br>■ Increase use of disparities data at site level for program planning and evaluation<br>■ Implement one evidence-based intervention for disparities in any pillar |

Information Technology Expansion and Information Exchange supports all program efforts

# NCCCP Template for Community Outreach

This tool provides a guide to focus outreach program planning in an effort to reduce cancer healthcare disparities. The tool outlines specific activities (e.g., define target populations, determine potential partners and partnership goals, establish expected outcomes, develop metrics, document barriers, assess effectiveness of interventions) and provides an overview of actions and considerations that will help implement strategic community outreach efforts.

## NCCCP Template For Community Outreach

| Activity | Action | Considerations |
|---|---|---|
| Define target population and define targeted project activities | Review community data, surveys or other local or state processes.<br>Determine a significant unmet need (e.g. Hispanic women at risk for breast cancer) | Cancer outreach, screening, and follow-up efforts for the NCCCP project would target these populations and *this specific effort*<br>Select only one Native American tribe if working with the Native American community |
| Determine partners and focus | Define the purpose/goal of the partnership | *For this specific effort*, consider potential partners (FQHC, faith based effort), efforts already serving the population that may result in a partnership, and/or formation of an advisory group with members of the community |
| Define scope, objectives/goals and expected outcomes | Determine scope for *this specific effort* (e.g. track screening through resolution of abnormal finding; track screen- ing through treatment, promo- tion of clinical trials, follow up care, and survivorship)<br>Determine effective and measurable strategies/targets | Consider:<br>■ whether information can be tracked<br>■ community input and/or experience from other providers/community groups<br>■ culturally appropriate materials<br>■ consult with NCI or advocacy group resources as needed |
| Develop metrics and proposed targets | Determine baseline and change for *this specific effort* during the project timeframe | Breast cancer tracking and proposed colon cancer tracking tool may offer a useful template |
| Document barriers | Note strategies to overcome barriers for *this specific effort* | Flag items for discussion on monthly calls or initiate connections with other sites |
| Evaluate | Assess effectiveness of *this specific effort* to make changes in interventions or overcome barriers. | Note ongoing barriers and share successes with other sites and NCI, through quarterly reports, e-mail updates, or agenda items for discussion on monthly calls |

### Resource Links:

1. The CDC has a web site that links to state cancer registry data and provided other cancer program information (http://apps.nccd.cdc.gov/cancercontacts/npcr/contacts.asp)
2. The Department of Health and Human Services (HHS) has a county-level Community Health Status Indicators web site (http://www.communityhealth.hhs.gov/homepage.aspx?j=1).
3. The NCI has a web link on community interventions and research resources. (http://rtips.cancer.gov/rtips/index.do).

Template was developed as part of the Disparities Vision and Program Overview which was approved by the Pilot Executive Committee December 16, 2008. Updated April 6, 2010

Version 3.0

# NCCCP Breast Cancer Screening Tracking Tool

This is a quality improvement tool to monitor the lag time between initial screening for breast cancer, diagnosis, treatment and recruitment for clinical trials, particularly for the underserved. The tool is a spreadsheet that records patient demographics, screening and diagnostic information, treatment information, and patient navigation details.

# NCCCP BREAST SCREENING TRACKING TOOL – Version 2.0

| Patient Name | DEMOGRAPHICS | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | City | Zip | Day Phone | Ethnicity | Race | Marital Status | Age Range | Insurance | Other | Activity that caused person to be screened (if any) |
| | | | | | | | | | | | |
| | ABNORMAL FINDINGS | | | | | | | | | | |
| | Breast Exam Result and Date | Screening Mammogram Result and Date | Diagnostic Mammogram Result and Date | Ultrasound Result and Date | MRI Result and Date | | | | | | |
| | | | | | | | | | | | |
| | DIAGNOSTIC INFORMATION | | | | | | | | | | |
| | Date of Diagnosis/Resolution | Diagnosis | Definitive Diagnosis by: (what test) | Biopsy Results | Stage of Diagnosis | Estrogen Status | Progesterone Status | HER2/NEU | Other | | |
| | | | | | | | | | | | |
| | TREATMENT INFORMATION | | | | | | | | | | |
| | High Risk Counseling Date | Genetic Test Results/Date | Clinical Trial Offered (Y/N) | Reasons not on Trial | Presented at Multi-Disciplinary Clinic/Conf prior to start of treatment? | Time from definitive diagnosis to first appointment for treatment consult | Surgery Date | Type of Surgery | Surgeon/ Physician | | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | Chemotherapy | | | | | Radiation Therapy | | | | | |
| | Date Started | Type of Chemo | Date Completed | Physician | Hormonal Therapy | Date Started | Type of Radiation | Date Completed | Physician | | |
| | | | | | | | | | | | |
| | NAVIGATOR | | | | | | | | | | |
| | Name | Date Connected with Patient | Navigation Started | Referrals to Other Services (List) | Barriers to Care | Reasons for not completing testing/treatment | | | | | |
| | | | | | | | | | | | |

# NCCCP Clinical Trials Minority Matrix / Strengths, Weaknesses, Opportunities, Threats (SWOT) Analysis

The Minority Matrix/SWOT analysis tool can be used to define the minority or underserved populations served, collect information about the community's demographic makeup, identify strengths and weaknesses of factors that influence clinical trial accruals, and improve accrual of underrepresented populations to clinical trials.

## Step 1: Please list focused underserved populations in order of priority in the "Step 1" boxes (next page).

## Step 2: Please complete the following fields for each population listed and served by your site:

**Percentage of all patients served:** The goal is to show the demographic makeup of your community. First calculate the number of people in your area served by your hospital. This is based on the entire population of the primary service area (based on zip codes and county data). Using that number, then calculate the percentage of those people who fall into the category listed (White, Elderly, etc.) For example, if 1 million people are served by your hospital and 100,000 are White, you would enter "10%" into the matrix for that section.

**Strengths:** Provide a short description of attributes of the site that have helped with your site's accrual of this population. (eg, internal support is available for many educational health fairs in these communities)

Accrual of this population at your site. (eg, no personnel at the site who are of this race/ethnicity)

**Opportunities:** Provide a short description of external factors that have helped reduce barriers and increase accrual for this population. (eg, a new nonprofit wants to partner with us)

**Threats:** Provide a short description of external factors that are harmful to accrual of these populations (eg, decrease in federal funding)

## Step 3: At the bottom of the matrix is a list of factors that can influence accrual. Fill out SWOT information for each of these factors.

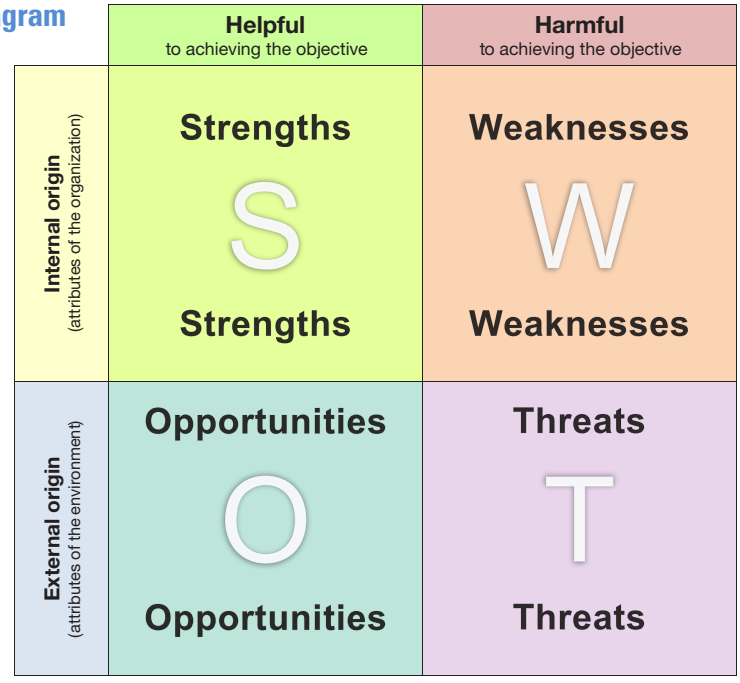
Accrual at your site (eg, Research infrastructure includes an IRB with a strong understanding of oncology)

**Weaknesses:** Provide a short description of attributes of the site that are harmful to underserved accrual at your site (eg, no knowledge of Patient Advocate opportunities)

Underserved accrual (eg, Community Partnership opportunity is having Komen's headquarters next to our office)

Undeserved accrual (eg, a nonprofit that is our major community partner just lost its key staff member)

## SWOT Analysis Diagram



## SWOT Analysis Diagram

| | |
|---|---|
| **Step 1: Focused Underserved Population(s)** Please list focused underserved populations in order of priority in the yellow boxes. | |
| | |
| | |

**Step 2:**
**After entering the focused underserved populations above, complete all boxes below for all populations you serve.**

| Population | White |
|---|---|
| Percentage of Total Population Served | % |
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| Population | Elderly (65 and older) |
|---|---|
| Percentage of Total Population Served | % |
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| Population | Black or African American |
|---|---|
| Percentage of Total Population Served | % |
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| Population | Asian |
|---|---|
| Percentage of Total Population Served | % |
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| Population | Rural |
|---|---|
| Percentage of Total Population Served | % |
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

## NCCCP Minority/Rural Matrix

| Population | Hispanic/Latino |
|---|---|
| Percentage of Total Population Served | % |
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| Population | American Indian or Alaskan Native |
|---|---|
| Percentage of Total Population Served | % |
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| Population | Native Hawaiian or other Pacific Islander |
|---|---|
| Percentage of Total Population Served | % |
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| Step 3: | |
|---|---|
| | Information Systems Tracking |
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| | Institution Infrastructure |
|---|---|
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| | Research Infrastructure |
|---|---|
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| | Minority Navigator Personnel/Program |
|---|---|
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| | Internal Resources "Ethnic Resources"<br>(Please include information for ANY population your site is focusing on for this project) |
|---|---|
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

## NCCCP Minority/Rural Matrix (Contd.)

| | Community Partnerships |
|---|---|
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

| | Patient Advocates |
|---|---|
| Strengths | |
| Weaknesses | |
| Opportunities | |
| Threats | |

Version 2.0 (3/2011)

# NCCCP Clinical Trials Screening & Accrual Log

This tool was a web-based application to track patients screened and enrolled in clinical trials. A case report form (CRF) of the online Log is provided to show the data collection elements. The tool tracked patient demographic information and performed data analysis. The data identified individual and site accrual barriers to help develop strategies to increase clinical trial participation among patients.

## Clinical Trial Screening and Accrual Log

This CRF corresponds to the electronic version of the Log hosted by NCI.

Patient Identification Number: XXXXXXXX

Record the Patient ID for your records

1. Date of patient screening (ex. MM/DD/YYYY):

### Patient Demographics

2. Ethnicity (select only one): ☐ Hispanic or Latino ☐ Non-Hispanic/Latino ☐ Unknown

3. Race: ☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander
☐ Asian Black or African American ☐ White ☐ More Than One Race ☐ Not Reported, Patient Refused
☐ Not Reported, Data Not Available ☐ Unknown, Patient Unsure of Race

4. Gender (select only one): ☐ Male ☐ Female

5. Age (ex 43):

### Protocol Screening Methods

6. Protocol for which the patient was screened (select only one): Definitions on page 16.

☐ GOG 0273 Chemotherapy Toxicity (Cancer Control)
☐ CALGB 80702 (Adjuvant Stage III Colon)
☐ CALGB 90601 (Advanced TCC)
☐ ECOG 1305 (1st line Rec/Met H&N)
☐ ECOG 1505 (Lung)
☐ ECOG 1609 (Melanoma)
☐ ECOG 5508 (Maint. NSCLC)
☐ NSABP B-43 (Breast DCIS)
☐ NSABP B-47 (Adjuvant Breast)
☐ SWOG 1007 (Adjuvant Breast)
☐ SWOG 0702 Obs ONJ Zoledronic Acid (Cancer Control)
☐ SWOG 0820 (Colon Prevention)
☐ SWOG 1115 (Metastatic Pancreatic)

7. What method(s) were used to identify this patient for protocol screening (select all that apply):

☐ Cancer/tumor registry
☐ Chart review
☐ Multidisciplinary/disease site conferences
☐ Pathology report
☐ Patient care rounds
☐ Patient self referral
☐ Patient navigator
☐ Pharmacy/chemotherapy list
☐ Provider referral: NCCCP investigator
☐ Provider referral: outside institution
☐ Provider referral: within institution
☐ Response to advertisement
☐ Review of clinic schedule
☐ Review of surgical schedule
☐ Tumor board

8. Was the patient navigator used in identifying the patient for screening: Yes No

9. If the patient navigator was involved, indicate how they were involved (select all that apply):

☐ Navigator obtained consent for treatment
☐ Navigator screened the patient
☐ Navigator referred patient to the research team

## Protocol Screening

10. Did the patient enroll in the protocol: Yes No

11. If the patient did not enroll in the protocol, indicate the reason why (select only one):

- ☐ Patient did not meet trial eligibility criteria (skip to question 13)
- ☐ Patient was eligible but declined participation (skip to question 15)
- ☐ Patient was eligible but MD declined to offer participation (skip to question 16)
- ☐ Patient was eligible but started treatment prior to completion of screening (skip to question 12)
- ☐ Patient was eligible but study suspended (skip to question 17)

12. If the patient was not captured prior to starting treatment, indicate reason why (select only one):

- ☐ Insufficient medical records at time of screening
- ☐ Patient not referred to the research team
- ☐ Recurring patient/ not new patient
- ☐ Urgency to initiate treatment

13. If the patient did not meet trial eligibility criteria, indicate the reason why (select all that apply):

- ☐ Abnormal labs
- ☐ Abnormal organ function
- ☐ Age criteria
- ☐ Allergy/intolerance to study related drug
- ☐ Co-morbidities
- ☐ Does not meet biomarker testing criteria
- ☐ Inappropriate stage, subtype, grade, or surgical margin
- ☐ Insufficient or unavailable pathologic samples for study
- ☐ Intolerance to study drug or related drugs
- ☐ No measurable disease
- ☐ Patient had progressive disease
- ☐ Performance status
- ☐ Prior therapy
- ☐ Prohibited medication
- ☐ Second cancer
- ☐ Time requirement from surgery or therapy

14. Skip---Question Was Removed from Log

15. If the patient was eligible but the patient declined participation, indicate the patient-related reason why (select all that apply):

- ☐ Cultural/religious issues
- ☐ No insurance coverage
- ☐ Did not keep appointment
- ☐ Palliative care/hospice
- ☐ Family member influenced against trial participation
- ☐ Patient declined to be retested per protocol
- ☐ Financial concerns/indirect costs (work, etc)
- ☐ Patient preferred another trial
- ☐ Insurance company denied coverage
- ☐ Perceived side effects/toxicities too great
- ☐ Insurance company refused to pay for additional testing
- ☐ Preference for standard treatment
- ☐ Lack of awareness/education about trials
- ☐ Preferred no treatment
- ☐ Language barrier/ lack of access to interpreter
- ☐ Refused to have re-biopsy or further tissue collection
- ☐ Lost to follow-up
- ☐ Second opinion/transfer of care
- ☐ Mistrust of research
- ☐ Social issues( Housing, childcare)
- ☐ No desire to participate in research
- ☐ Travel & transportation issues

16. If the patient was eligible but the MD declined to offer participation, indicate the physician-related reason why (select all that apply):

- ☐ Concerns over patient non-compliance/lack of social support
- ☐ Drug unavailability
- ☐ Insurance denied coverage
- ☐ Insurance company refused to pay for additional testing
- ☐ Lack of adequate reimbursement
- ☐ Lack of knowledge/awareness of the trial by MD/ Research staff
- ☐ Lack of MD/Research staff to offer patient the trial
- ☐ Lack of time for MD/Research staff to offer patient the trial
- ☐ Language barrier/lack of access to interpreter
- ☐ Medical concerns re: Comorbidities not included in eligibility
- ☐ Medical concerns re: patient tolerating treatment/ performance status

☐ Non-participating MD

☐ Patient referred out

☐ Physician declined to have patient retested per protocol

☐ Preferred to offer palliative care

☐ Preferred to offer different trial

☐ Preferred to offer no treatment

☐ Preferred to offer standard of care

☐ Refused to have re-biopsy or further tissue collection

17. If there was a language barrier, indicate the language spoken (select only one):

☐ Chinese ☐ Filipino ☐ French ☐ Japanese
☐ Korean ☐ Russian ☐ Spanish ☐ Vietnamese
☐ Hmong ☐ Italian ☐ Somalian ☐ Hungarian

18. Is the patient rural per NCCCP/site criteria? Yes No

## Protocol Screening Definitions

**GOG 0273:** Elderly (age > 70 years) stage I-IV previously untreated primary ovarian, peritoneal, or fallopian tube cancer

**CALGB 80702:** Completely resected Stage III colon adenocarcinoma and no prior chemotherapy.

**CALGB 90601 (Advanced Uroepithelial Neoplasm):** Locally advanced or metastatic urinary tract transitional cell CA with no prior chemotherapy for metastatic disease.

**ECOG 1305 (1st line Rec/Met H&N CA):** Loco regional recurrent or metastatic Squamous Cell Carcinoma of the Head and Neck without prior chemotherapy for recurrent or metastatic disease.

**ECOG E1505 (Lung):** Resected non-small cell lung carcinoma Stage IB – IIIA less than 12 weeks post resection

**ECOG E1609 (Melanoma):** Completely Disease free, Surgically resected, Stage IIIb, IIIc,M1a or M1b

**ECOG E5508 (Maint. NSCLC):** Stage IV nonsmall cell, nonsquamous cell lung CA and no prior advanced stage disease chemotherapy.

**NSABP B-43 (Breast DCIS):** Female breast DCIS following lumpectomy.

**NSABP B-47 (Adjuvant Breast):** Resected invasive breast CA Stage II and III with T1 to T3, low Her-2, and no neoadjuvant chemotherapy.

**SWOG S0702 ONJ – Zoledronic Acid (Cancer Control):**

i. Bone involvement by Multiple Myeloma, Solid Tumor Neoplasms, or other malignancy with an indication for IV bisphosphonate therapy.
ii. No prior IV bisphosphonate therapy or IV bisphosphonate therapy of < 90 days prior to registration.

**SWOG 1007 Adjuvant Breast:** Node positive 1-3, Hormone Receptor positive, HER2 Neg

**SWOG 0820 Prevention Colon:** Stage 0,I,II or III Colon Cancer have been treated with standard of care and are one year +/– 3 months of surgery.

**SWOG 1115 Metastatic Pancreatic:** adenocarcinoma with one and only one prior line of gemcitabine chemotherapy or progression within 6 months of adjuvant therapy.

## Log Entry Guidance

**Instructions:** The chart below is intended to help you easily locate a Log answer choice for your patient. Follow the steps below to help guide your data entry into the online Log.

**Step 1:** Find your patient's scenario in the "Patient Scenario" column below.

**Step 2:** Look in the column to the right ("Suggested Action") to see guidance on how to enter the patient's information into the Log.

**Step 3:** If you're still unsure, email the Log Support Team at NCINCCCPLogSupport@mail.nih.gov.

| Log Question Number | Patient Scenario | Suggested Action |
|---|---|---|
| ID of Patient for screening (Q7) | Non-MD referrals | Select one of the following answer options:<br>■ "Provider referral: NCCCP investigator"<br>■ "Provider referral: within institution"<br>■ "Provider referral: outside institution" |
| Protocol Screening | | |
| Reason Not Enrolled (Q11) | Language barrier | Select "Patient was eligible but MD declined to offer participation" in Q11, then select "Language barrier/lack of access to interpreter" in Q16. |
| | Patient did not have cancer | DO NOT ENTER PATIENT INTO LOG |
| | Patient does not meet protocol screening definition (definitions can be found in CRF) | DO NOT ENTER PATIENT INTO LOG |
| Eligibility-Related (Q13) | Incomplete or different pathology | DO NOT ENTER PATIENT INTO LOG until final pathology |
| | Inappropriate stage/grade | DO NOT ENTER PATIENT INTO LOG until final staging/ pathology |
| | On other drugs, e.g., statin | Select "Prior therapy" |
| | Incomplete staging | DO NOT ENTER PATIENT INTO LOG |
| | Too low or high Oncotype score | Select "Does not meet biomarker testing criteria" |
| | Unknown | DO NOT ENTER PATIENT INTO LOG until you have talked to MD to close the loop |
| | Metastatic disease | Select "Patient had progressive disease" |
| | Patient expired during the screening process | Select "Patient had progressive disease" |
| Patient-Related (Q15) | Did not keep appointment | Select "Lost to follow-up" |
| | Unknown | DO NOT ENTER PATIENT INTO LOG until you have talked to MD to close the loop |
| | Study closed | DO NOT ENTER PATIENT INTO LOG |
| MD-Related (Q16) | Dementia/cognitive problems | Select "Medical concerns re: Co-morbidities not included in eligibility" |
| | Medical concerns re: age/frailty of patient | Select "Medical concerns re: Co-morbidities not included in eligibility" |
| | Unknown | DO NOT ENTER PATIENT INTO LOG until you have talked to MD to close the loop |
| | MD preferred other Rx | Select "Preferred to offer standard of care" OR "Preferred to offer different trial" |

NCCCP Clinical Trial Screening and Accrual Log

Version Date: August 1, 2013

# NCCCP Clinical Trials Best Practice Matrix

This tool was designed and used by the NCCCP sites to assess, measure, and report progress on their clinical trial infrastructure capabilities. The self-assessment tool included clinical trial site best practice characteristics—or 'attributes'—such as CT portfolio diversity, physician engagement in CTs, multidisciplinary team involvement, education standards, and underserved community outreach and accrual. The NCI's understanding of the tool's value to the NCCCP hospitals led to a formative evaluation in collaboration with the University of North Carolina. Based on input from multiple stakeholders in the community oncology setting (e.g., ASCO Community Research Forum, community investigators), the tool attributes and indicator levels were refined in 2014. The revised tool has been renamed the Clinical Trials Assessment of Infrastructure Matrix (CT AIM); it was presented at ASCO's 2014 Annual Meeting as well as the Quality Symposium, and a manuscript about the revision process and the current version of CT AIM is underway.

## Best Practice Clinical Trial Site Characteristics

Original draft created by Dr. Steve Grubbs, Christiana Hospital and members of the 2007 Best Practices Work Group for NCCCP. * Version 1.0 Approved by CT Subcommittee on 4/19/2011

| Best Practice | Level 1 | Level 2 | Level 3 |
|---|---|---|---|
| 1. Physician Engagement in Clinical Trials | Informal physician support and inconsistent engagement with clinical research staff and site administration. | One or more physicians committed to implementing clinical trials and overseeing and empowering clincal research staff to successfully perform trials. Some engagement with site administration and other sites (if applicable). | Designated "Physician Champion(s)" are recognized at the site for their clinical trial expertise and oversight of the clinical trials program; performs consistent engagement of other disciplines, specialties and administration throughout the site. |
| 2. Education Standards | Formal Basic Human Subject Protection education completed by all clinical research professionals and investigators. | Minimum of 50% of non-investigator clinical research professionals are credentialed as a certified research professional and/or oncology nurse within three years of hire. Physicians remain engaged in current issues in their specialty or sub-specialty. | All investigators Board Certified when possible. Minimum of 75% of non-investigator clinical research professionals are credentialed as a certified research professional and/or oncology nurse within three years of hire. |
| 3. Quality Assurance | Adherance to ICH GCP; Site has addressed management of clinical trial operational processes (e.g., guidelines, SOPs, Policies/Procedures), Less than 50% of SOPs in place (see Table 2. Zon et al, JCO, 2008 below); PI is compliant with IRB rules, regulations and decisions. | Adherance to IHC GCP, Internal and external audits with 80% acceptable, acceptable with follow-up; unacceptable scores result in changed policy; 50-74% of SOPs in place (see Table 2. Zon et al, JCO, 2008 below); Regular SOP review and modifications implemented based on audits and sponsor findings. PI available to the IRB. | Consistent acceptable, acceptable with follow-up performance on external audits; Site is audit-ready at all times; Site in good standing with sponsors; Greater than 75% SOPs in place (see Table 2. Zon et al, JCO, 2008 below); PI consistently works with IRB when need identified. |
| 4. Clinical Trial Portfolio Diversity and Management | Site/Investigator goals for screening and accrual established; Phase III treatment trials active | Phase II, cancer control, prevention, and QOL trials and at least 4 different disease sites; regular review of trial diversity and status of activated trials occur to monitor perfomance/analyze issues of poor accruing trials | Phase I or Phase I/II, tissue procurement, and more than 4 different disease sites; proactive trial portfolio management; research team routinely addresses poor accruing trials |
| 5. Participation in the Clinical Trial Process | Investigator and clinical research professionals attend research sponsors meetings. Active NCCCP trial log participation. | Physicians assume a leadership role of co-investigator or local PI of a trial or trials. Investigators participate in internal scientific review committees and/or IRB. Active Screening and Accrual Log data entry with periodic use of Barrier Reports to guide addressing identified barriers. | Investigators are more active in Cooperative Group Regional or National Research Consortiums. PI consistently works with IRB when need identified. Consistent Screening and Accrual Log Data entry with consistent Barrier Report use to guide corrective action to address identified barriers. |
| 6. Multidisciplinary Team Involvement | Tumor Board with medical, radiation, and surgical oncology review of trial participation feasibility. | Formal Multidisciplinary Conferences (MDC) with active participation of clinical trial team (e.g. review of trial eligibility) and participation in at least 4 disease sites | Level II and participation in more than 4 disease sites; Multidisciplinary Clinic(s) with research staff participation |
| 7. Accrual Rate (annual patients entered on treatment, cancer control or prevention and translational trials divided by annual site new analytic cases) | Less than 5% | 5% to less than 10% | 10% or greater |

| Best Practice | Level 1 | Level 2 | Level 3 |
|---|---|---|---|
| 8. Underserved Community Outreach and Accrual For the NCCCP, we define the populations affected by health disparities to include racial and ethnic minorities, and other underserved populations: residents of rural areas, women, children, the elderly, persons with disabilities, the uninsured, underinsured and those who are socioeconomically disadvantaged. | Formal plan and activities to improve underserved community outreach and population accrual. | Underserved population accrual is at least 50% of the percent of underserved population at a site. (See TABLE 1 below). Refinement of formal plan based on community feedback through outreach efforts. | Underserved population accrual is at least 75% of the percent of underserved population at a site. (See TABLE 1 below). Ongoing community involvement and communication with the research team. |
| 9. Clinical Trial Communication and Awareness | Oncology community trial education and communication through protocol meetings, tumor boards, Multidisciplinary Conferences and support when initiating trials in the community. | General medical community (non oncology physicians, nurses, hospital administrators) trial education and communication through written publications (newsletters, professional journals, specific trial updates); inservices; and in-office updates. | Lay community trial education and communication through community outreach; clinical trial advocacy committees; community organization interaction and established Community Advisory Board. |

## Score:

1. Physician Engagement in Clinical Trials _____
2. High Education Standards _____
3. Quality Assurance _____
4. Clinical Trial Portfolio Diversity and Management _____
5. Participation in the Clinical Trial Process _____
6. Multidisciplinary Team Involvement _____
7. High Accrual Rate _____
8. Underserved Community Outreach and Accrual _____
9. Clincal Trial Communication and Awareness _____

**Total Score:** _____

Scoring Range: 9-27

## References:


1. Baer, A. R., Cohen, G., Smith, D. and Zon, R. (2010). Implementing Clincal Trials: A review of the Attributes of Exemplary Clinical Trials Sites. *JOP* (6) 6, 328-330.
2. Zon, R., Cohen, G, Smith, D., Baer, A. (2011). Part 2: Implementing Clinical Trials: A Review of Attributes of Exemplary Clincal Trial Sites. *JOP*, (7) 1, 61-64.
3. Zon, R., Meropol, N. J., Catalano, R. B., Schilsky, R. L. (2008). American Society of Clinical Onocology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites. *JCO*, (26) 15, 2562-2567.


TABLE 1: Underserved Accrual example 1:Site A's tumor registry has a 2.0% Native American population (e.g., 500 patients, 10 of which are Native American). To reach Level II underserved accrual on the matrix the site would need to meet or exceed 50% of the site's 2% Native American population times the entire accrual. So if entire accrual = 100 and 2% are Native American (or 2 patients based on registry percents) then 50% of those 2 patients, or 1 patient needs to be accrued. To reach Level III in the same scenario then 90% or 1.8 patients need to be accrued.

TABLE 1: Underserved Accrual example 2: A site's catchment area has a 10% Hispanic population (100 of 1000 patients). To reach Level II underserved accrual on the matrix the site would need to meet or exceed 50% of the sites 10% Hispanic population times the entire accrual. If the site accrued 200 patients onto trials, and 10% are Hispanic (based on catchment) (10% = 20 patients x 50% = 10 ) then 10 Hispanic patients would need to be accrued. To reach Level III 75% or 15 Hispanic patients would need to be accrued.

TABLE 2. Suggested SOP Topics (Zon et al, 2008. JCO (26) 15)

Preparation and maintenance of SOPS; training on SOPs

Adverse event reporting

Clinical study operations

Managing clinical study supplies

Communication documents

Coordinator selection, qualification, responsibilities, and training

Data management

Informed consent

Investigator agreements

Investigator and subinvestigator selection, qualifications, responsibilities, and training

IRB approval and operations for clinical studies

Prestudy requirements

Protocol handling, review of feasibility, and approval

Quality control

Recruitment methods

Regulatory documentation

Sponsor interactions

Close-out study activities

Study confidentiality

Drug accountability and storage

Chart storage

Scientific misconduct policies and procedures

## Abbreviations:

**SOP**, standard operating procedure

**IRB**, Institutional review board

# NCCCP Cancer Genetic Counseling Assessment Tool

This tool defines the minimal genetic counseling service requirements. The tool measures the key components of a cancer genetics program based on NCCN guidelines for genetic risk assessment and can be used to guide program development.

## Cancer Genetic Counseling Assessment Tool

| Components | Elements / Definition | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|---|
| Patient Identification | Potential patient numbers based on 20% of applicable yearly analytic cases having hereditary and/or familial predisposition for:<br>■ Breast, Breast/Ovary<br>■ Colon, Colon/Uterine<br>■ Other<br>● Genodermatoses<br>● Thyroid<br>● Renal/neuroendocrine<br>◆ Pediatric | 0-20% of appropriate patients identified | 21-40% of appropriate patients identified | 41-60% of appropriate patients identified | 61-80% of appropriate patients identified | 81-100% of appropriate patients identified |
| Physician Referrals | Subtypes of clinicians:<br>■ Tier one- top referring physician subtype (ex. Medical oncology)—always to often refer<br>■ Tier two-refers occasionally to often<br>■ Tier three-rare to few referrals | Majority (>90%) of referrals from one Tier one | 85% Tier one<br>15% tier two | 75% tier one<br>20% tier two<br>5% tier three | 70% tier one<br>25% tier two<br>5% tier three | 60% tier one<br>30% tier two<br>10% tier three |
| Services provided | Cancer Genetics Service lines:<br>■ Breast, Breast/Ovary<br>■ Colon, Colon/Uterine<br>■ Other<br>● Genodermatoses<br>● Thyroid<br>● Renal/neuroendocrine<br>● Pediatric | Majority (>90%) of cancer genetics consultations occur for one service line | 85% one service line with at least 15% occurring for a second service line | 75% one service line with at least 20% occurring for a second service line 5% from third service line | 70% one service line with at least 25% occurring for a second service line 5% from third service line | 60% one service line with at least 30% occurring for a second service line 10% from third service line |
| Pre-test counseling | 3-4 generation pedigree<br>Evaluation of the personal and family history to determine what, if any, genetic testing is appropriate<br>Run risk assessment models as appropriate<br>Provide all elements for ASCO informed consent† | 0-1 components of pre-test counseling provided | 2 components of pre-test counseling provided and/or components provided episodically | 3 components of pre-test counseling provided routinely | All components of pre-test counseling routinely provided | Level 4 plus utilization of computer applications for pedigree drawing and risk calculation |
| Post-Test Counseling | Genetic test results disclosure and interpretation in the context of the personal and family history<br>Cancer risk estimates based on genetic test result or empiric data<br>Recommendations for cancer screening and prevention<br>Discuss risk reduction surgeries if appropriate<br>Educational resources and referrals given as needed<br>Discuss additional genetic testing options | 0-1 components of post-test counseling provided | 2-3 components of post-test counseling provided and/or components provided episodically | 4-5 components of post-test counseling provided routinely | All components of pre-test counseling routinely provided with utilization of computer applications for risk calculation when available | Level 4 plus at least one of the following:<br>■ Patient is referred to long term follow up program<br>■ Research options are reviewed<br>■ Resources are provided to the patient to assist w/ dissemination of information to family members |

| Components | Elements / Definition | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|---|
| Documentation of the Cancer Genetics Consult in the Patient's Medical Record | Personal History<br>Family History<br>Initial Impression<br>Genetic Testing Recommendations<br>Test Result<br>Result Interpretation<br>Cancer Risk Estimates<br>Summary Management Recommendations | Limited to no documentation in the patient's medical record | N/A | Applicable elements documented in the patient's medical record | N/A | Level 3 plus copies distributed to the patient and his/her physicians |
| Financial | | No billing occurs for pre- or post-test counseling sessions | NA | Billing for pre- and post-test counseling session is episodic (ex. Only when MD is present) | NA | Global billing for pre- and post-test counseling session |

† ASCO Informed Consent Elements Described below

## American Society of Clinical Oncology Policy Statement Update: Genetic Testing for Cancer Susceptibility

Adopted on March 3, 2003, by the American Society of Clinical Oncology

**Table 1. Basic elements of Informed Consent for Cancer Susceptibility Testing**

1. Information on the specific test being performed
2. Implications of a positive and negative result
3. Possibility that the test will not be informative
4. Options for risk estimation without genetic testing
5. Risk of passing a mutation to children
6. Technical assuracy of the test
7. Fees involved in testing and counseling
8. Psychological implications of tests results (benefits and risks)
9. Risks of insurance of employer discrimination
10. Confidentiality issues
11. Options and limitations of medical surveillance and strategies for prevention following testing
12. Importance of sharing genetic test results with at-risk relatives so that they may benefit from this information

# NCCCP Multidisciplinary Care (MDC) Program Self-Assessment Tool

This tool defines an MDC model for cancer care in the community and describes the key indicators (i.e., case planning, physician engagement, coordination of care, infrastructure, and financial considerations) to measure the level of MDC implementation. The self-assessment tool may be used by community cancer centers to create and/or expand MDC programs.

## MDC Assessment Tool

| Assessment Area | Educational conference (tumor board) that does not impact treatment planning. Retrospective review of cases | Elements of the Multi-Disciplinary Care continuum Prospective review of cases<br>For the definition of "prospective" please see the Commission on Cancer program eligibility requirement E3 (page 35) of the 2012 Cancer Program Standards<br>Elements present may reflect institutional variability of site-specific disease burden and patient volume |
|---|---|---|

| | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| **Case Planning** | Case planning and treatment is performed by individual physicians without input from a multidisciplinary conference. Patients present to multiple physician offices on different days. | <25% of case planning is done through a multidisciplinary conference which occurs on recurring basis. | 25-75% of case planning is done through a multidisciplinary conference which occurs on recurring basis. | >75% of case planning is done through a multidisciplinary conference which occurs on recurring basis. | All case planning is done through a multidisciplinary conference which occurs as the patient encounters care |
| **Physician Engagement** | Diagnostic and treatment Physicians belong to multiple independent groups, with little interaction. | Diagnostic and treatment Physicians belong to multiple independent groups, and each group is actively engaged with the cancer center | The cancer center is implementing a Conditions of Participation agreement, and physicians are actively engaged in developing treatment standards | Same as prior with the addition of engagement for strategic direction. Majority of physicians have signed Conditions of Participation. | Same as prior with the addition of physicians who have clinical operational authority for the MDC. All Physicians have signed Conditions of Participation. |
| **Treatment Team Integration** | Sporadic integration of diagnostic and treating physicians (<80%) | Consistent integration (=> 80%) of case appropriate diagnostic and treating physicians. | Same as prior; Integration of additional allied health practitioners (e.g., nutrition, PT/OT, palliative care, genetic counselors, mental health practitioner) | Same as prior; all members of MDC team participate in treatment planning by consensus. | Same as prior; Primary Care Physician is consistently notified of treatment plan. |
| **Integration of Care Coordinators** (includes but is not limited to Nurse navigators, Navigators, Survivorship Nurses, Social Workers, and Case Managers) | Patient care is episodic. Patient has to present to multiple locations on different days for treatment and or diagnostic modalities. Information is stored in multiple locations, and difficult to coalesce. No Care Coordinators. | A Care Coordinator is available if needed to arrange treatment and diagnostic modalities to make care less episodic. Information is coordinated and is readily available to physicians and staff. | Same as prior with a Care Coordinator engaging <25% of patients at least once during their treatment. | Same as prior with a Care Coordinator engaging 25-75% of patients at least once during their treatment | Multiple Care Coordinators are utilized for >75% of patients from the point of initial contact through survivorship. A system to track interventions that lessen barriers to efficient care is used by care coordinators |
| **Infrastructure** | Limited physical infrastructure. Hospital, physician office model | NA | Some dedicated physical facilities which do not cover the full spectrum of care | NA | Dedicated cancer center with ability to provide the full spectrum of care to patients |
| **Financial** | Billing is episodic based on encounter with facility or physician. No facility fee is applied. | NA | Physicians bill separately. Facility fee for MDC. Prospective financial counseling available to patient. | NA | Global bill for MDC billing inclusive of facility fee. Prospective financial counseling available to patient. |

| | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| **Clinical Trials** | Patients not screened for eligibility for clinical trials. Patients not informed about clinical trial options. | NA | All patients screened for trial eligibility and availability; clinical trials staff present at MDC. | NA | Same as prior; Clinical trials staff reviews all eligible charts, engages care coordinators and treating physicians prior to initial treatment. |
| **Quality Improvement** | National care guidelines not used to guide treatment | National care guidelines are used as a framework for decision making. | Same as prior with QOPI and/or RQRS data used to guide quality improvement initiatives in the hospital and physician offices | Same as prior with patient survey data (any type) used to guide quality improvement initiatives | Same as prior with a structured compliance review process in place to measure guideline adherence and guide quality improvement initiatives. |
| **Medical Records** | Medical records are not integrated. Little to no sharing. Mixture of paper and EMR. | N/A | >50% of cancer physicians have an integrated EMR and/ or major IT functions shared with the cancer center | N/A | > 75% of cancer physicians have an integrated EMR and/ or major IT functions shared with the cancer center to provide access to information across the care continuum. |

MDC Assessment Tool—Version 3.1
V3.0 approved by NCCCP Executive Subcommittee 3-10-2011
V3.1 approved by NCCCP QOC Subcommittee 12-19-2012
This Tool has not been validated

# NCCCP Navigation Program Self-Assessment Tool

This self-assessment tool can be used to build or advance a navigation program based on criteria discussed in each category. Each category represents a component of patient navigation that should be present in any program. The levels of the tool provide a way to advance from the minimum to a benchmark status.

## NCCCP Navigation Assessment Tool

As all navigation programs are built uniquely, we encourage you to rate your program as you feel appropriate. The purpose of this form is not to gauge one program against another, but to assist you in building a stronger navigation program. This form can be used to assess an individual tumor site or the entire program.

### Definitions:

**Key Stakeholders:** Those people that you feel are essential to making a program work. Include Administration, Navigators, Staff, Physicians (both employed and private practice). Specialty areas include medical, surgical and radiation oncology, rehab, palliative care and hospice.

**Community Partnerships:** Those entities that exists within and outside of your program that you need the support of or are a referral source for patient use and contribute to the support of the patient along the continuum of their care.

**Acuity System:** Ability to determine appropriate level of care/intervention based on patient need and disease process.

**Risk Factors:** Variable associations with increase risk of complications with disease and treatment of cancer.

**Metrics/Reporting Measures:** Measuring activities and performance

**Percentage of Patients Navigated:** Cancer Patients inclusive of Analytic cases, new diagnosed primaries, **reoccurrences, advanced diseases, metastatic of defined cancer site(s) within your program setting.**

**Continuum of navigation:** Navigation functional areas includes: Outreach/Screening, Abnormal finding to Diagnosis, Treatment, Outpatient &/or Inpatient, Survivorship and end of life care. Navigation can occur along any of or all of these. One single person may do all of these, or you may have one person designated to cover one area of the continuum. They may be disease specific navigators, or cover all diseases within that category. The sign of a level five site is that navigation is continuous across the cancer care continuum.

**Disparity:** Is any under-represented group that your program is able to focus on. Providing outreach and effort in this population is a hallmark of Navigation according to its original conception and should be continued as part of a navigation program.

**Tools for Reporting Navigator Statistics:** Documents to help evaluate and measure a navigation program.

**MDC Involvement:** Multidisciplinary team approach to care including physicians ( med onc, rad onc, and surgeon) and other healthcare providers to create plan of care for patient; patient may not always be present to be considered an MDC.

| | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| Key Stakeholders* | Administrative support | At least one physician champion referring to Navigation Program | Two physicians involved and referring to Navigation Program; one is not an oncologist. | Most Specialty physicians support the Navigation Program. | The Navigation Program receives referrals from employed and non-employed MDs PCPs, or community partners. |
| Community Partnerships* | Navigator works with departments outside of cancer but within own facility | **Plus**, works with at least one national group such as NCI, ACS, LLS, Wellness Community, Susan G Komen for the Cure, or LIVEstrong | **Plus** supports state cancer control goals & objectives. | **Plus** connects with other local community partners such as churches, community centers, other community organizations | Includes a formal connection to National/State/Local organizations as an active committee or board member |
| Acuity system/Patient Risk Factor* | No Risk Factor or Acuity system available | Some patients assessed but no formal tool is used. Acuity based on dependence of pt vs. actual patient risk factors. | Use of a formal tool which may be disease specific. | Utilizing formal assessment tool has a well defined referral process for identified issues. | Provides periodic re-evaluation as a proactive approach to intervene or prevent issues and ensure quality of care during specific treatment points. |
| Quality Improvement Measures* | None in place. | Brainstorming and discussion regarding metrics and reporting within the multi-disciplinary team or cancer committee. | One Quality Improvement (QI) initiative in place measured and reported to all stakeholders on hardcopy file annually. | QI initiatives developed in collaboration with Patient Feedback and/or Patient Satisfaction Surveys reported to Administration. | Multiple QI initiatives in place monitored to demonstrate program improvement and financial contribution and cost savings services of Navigation (ie compliance to POC). |

| | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| Marketing of the Navigation program | Occurs by word of mouth | Includes level 1 as well as some basic written material, i.e. Pamphlet | **Plus**, Navigator participation at health fairs, cancer screening events as a means of marketing cancer program | **Plus**, effort made to promote navigation in some media form | **Plus**, multiple sources of media used to support navigation (video, print, audio, web, etc) |
| Percentage of patients offered navigation | 0-20% of defined tumor site | 21-40% | 41-60% | 61-80% | >80% |
| Continuum of Navigation* | One functional area within the cancer navigation continuum | Two functional areas navigated within the continuum | Three functional areas navigated within the continuum | Four functional areas navigated within the continuum | Navigation across all functional levels of the continuum. |
| Support Services available and used by the Navigation Team | No Resources available | Hospital resources (SW and/or case manager) are available to assist with cases | Outpatient Social Services available within Cancer Program | Level three plus a minimum of two additional out patient oncology specific services available | All services available or can be accessed within the community or organization Dietitian, Social Work, psychologist, Clinical Trials, Speech Therapy Physical/ Occupational/ Pastoral Care, Oncology Rehab, Financial Counselor's, Palliative Care, Volunteer Dept., genetic counselor, survivorship. |
| Tools for reporting navigator statistics* | No reports or tools. Paper record (Pt Chart) narrative of services provided for patient and their family | Basic Home grown access file/word, excel Basic info tracked, i.e. number of pts, disease site, supportive services provided | High level home grown access database created. by hospital IT dept. Collects stats and support services provided for pt/ family. | Formal hospital system EMR database utilized to collect support services and stats. Not a database specific for Navigation. | Reporting of all support services provided to the patient via EMR specific for Navigation including outcome information. Document all support services. |
| Financial assessment | No Financial assessment performed | Financial assessment and assistance only available in the in-patient setting. | **Plus**, financial assessment and assistance available for out-patients within Cancer Program | **Plus**, proactive Financial assessment completed for all oncology patients | Plus, data collection completed on types of services provided and number of patients assisted on a regular basis. |
| Focus on Disparities* | None defined | Underserved population Defined | At least one culturally sensitive activity devoted to reaching underserved population provided annually | Patient service mechanism defined to integrate underserved patients into the program | Cultural sensitivity assessment completed on cancer center staff with cultural objectives created on at least an annual basis. |
| Navigator Responsibilities | Navigator is unaligned with any physician and responsible only for support of the Patient | **Plus**, Navigator coordinates care between multiple disciplines with in the cancer program | **Plus**, Navigator participation in Support Groups, Family/Patient center programs, | **Plus**, Navigator maintains an Active role in disease specific MDC/Tumor Conferences | **Plus**, Navigator is an integral part of Quality Improvement, audits, and strategic planning |

| | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| Patient Identification process | No formal patient identification. Path reports, daily schedule, radiology reports used to identify patients. | N/A | Patients self refer or are referred by Oncology Provider | N/A | Primary Care Provider and/ or specialist (GI, Pulmonary, Interventional Radiology) refers at the time of abnormal finding |
| Navigator Training | No formal training in place | Core Competencies of Navigation defined | Local/in-house training curriculum developed specific to navigator core competency and development of Navigator role | Local/in-house training program completed by all navigators -- Or are certified in Oncology in their respective disciplines | Navigators formally trained by nationally recognized training program and certified. |
| Engagement with Clinical Trials | Navigator shares basic understanding of clinical trials in cancer | Navigator has greater depth understanding of Clinical trials, has completed specific training (NCI, ONS, etc) | Navigator shares information regarding the availability of clinical trials in their community cancer center with patients | Navigator engages with research team in providing general referrals | Navigator engages with research team, assists with specific trial referrals for underserved populations |
| Multi-disciplinary Care/Conference Involvement* | Basic Commission On Cancer requirements met. Including discussion of NCCN guidelines or other National Oncology Standards | Navigator attends tumor conference but doesn't participate, documents physician discussion of plan of care in narrative note but not formal part of patient record | Navigator assists with Case finding for MDC presentations. No treatment plan documented, Dictation completed by MD re; plan of care. | Navigator provides formal review of discussion of MDC with patient after case presentation. | Patient informed of presentation at MDC with full formal report on treatment planned discussion shared with patient referring MD and primary care, formal audits completed. |

Items with an asterisk (*) are further explained under the definition section at the beginning of the Assessment Tool.

Navigation Assessment Tool Version 1.0 was created by the National Cancer Institute Community Cancer Centers Program (NCCCP) and approved by the NCCCP Executive Subcommittee on 7/14/2011.
**This tool has not been validated.**

# NCCCP Cancer Psychosocial Care Assessment Tool

This self-assessment tool for community cancer centers helps to evaluate and improve their psychosocial care services. The tool provides guidance for ensuring that the psychosocial needs of cancer patients are met. Psychosocial health services are those psychological and social services that enable cancer survivors, their families, and health care providers to optimize biomedical health care and to manage the psychological/behavioral and social aspects of cancer and its consequences so as to promote better health.

## NCCCP Cancer Psychosocial Care Assessment Tool Modeled for Whole-Person Care

**Psychosocial Health Services** are those psychological and social services that enable cancer survivors, their families, and health care providers to optimize biomedical health care and to manage the psychological/behavioral and social aspects of cancer and its consequences so as to promote better health.

### Multidimensional culturally informed psychosocial health needs screening to include:

- Emotional/Mental Health Needs (ie: anxiety, depression, coping, sexuality)
- Practical Problems (ie: concrete needs and illness-related concerns - financial, transportation, housing)
- Social Problems (ie: lack of social support/resources, vocational impact, insurance)
- Support Needs (ie: personal,social,medical, spiritual)

| Category | Elements for Consideration | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|---|
| **1. Communicates to the cancer survivor and family the importance of psychosocial needs and care** | ■ Letter<br>■ Brochures<br>■ Posters<br>■ Structured discussion with oncology healthcare team members | No systematic process in place | * | Communicates via at least one mechanism on at least one occasion | * | Communicates via multiple mechanisms on multiple occasions with participation from physicians; provides focused education on psychosocial needs |
| **2. Facilitates effective patient/provider communication**<br>a. Provides training in patient/provider communication for staff | ■ Creates rapport<br>■ Elicits patient perspective<br>■ Demonstrates empathy<br>■ Manages uncertainty<br>■ Shares decision-making<br>■ Enables patient self-management | No systematic process in place | * | Patient communication skills training available for patient care providers | * | Patient communication skills training required for all patient care providers |
| b. Monitors effectiveness of patient/provider communication | ■ Patient surveys<br>■ Provider surveys | No systematic process in place | * | Quality of communication assessed by patients on a random basis | * | Quality of communication assessed by patients on a routine basis |
| **3. Identifies psychosocial health needs of cancer survivors** | ■ Data collection method<br>■ Timing/periodicity | Not systematically done; reliance upon survivors to volunteer information or provider to observe or inquire during clinical conversations | Random/ inconsistent screening conducted | Screening consistently conducted using a standardized method with all survivors upon initial encounter/ treatment initiation | Level 3 **plus** when positive screen, a comprehensive assessment is also conducted | Level 4 **plus** reassessments covering defined timeframes from diagnosis throughout follow-up |

| | | | | | | |
|---|---|---|---|---|---|---|
| **4. Designs and implements psychosocial plan of care**<br>a. Links cancer survivor/ family with needed psychosocial services | | Culturally-sensitive psychosocial resources, services, and care strategies identified for meeting needs of survivors | Level 1 **plus** systematic referral pathways in place for addressing needs; staff trained in basic psychosocial needs | Level 2 **plus** mental health professional available on site for consultation | Level 3 **plus** mental health professional with training in care of cancer survivors is available on site to provide psychosocial services | Level 4 **plus** integration of comprehensive services with adequate mental health services available to meet the needs of all patients who need those services |
| b. Engages and supports cancer survivor in managing their illness and health | | Generic cancer survivor education materials available | * | Level 1 **plus** variety of media/ modes (ie: audio, visual, and/or opportunities for group learning, such as behavioral change programs) | Level 3 **plus** tailored education specific to cancer survivor/ family situation (type of cancer, treatment, language, literacy level) | Level 4 **plus** provision of therapeutic emotional support, including consultations and/or supportive materials, to address the behavioral change process |
| c. Coordinates psychosocial and biomedical care | | Initial psychosocial assessment data documented and available to healthcare team | * | Level 1 **plus** specific personnel responsible for psychosocial care management and interdisciplinary communication | * | Level 4 **plus** reassessment prompts, revisions to plan of care as appropriate, and follow-up communication with primary oncology team |

Survivorship & Palliative Care Subcommittee.
Psychosocial Care Assessment Tool Version 2.0 approved by the Executive Subcommittee on 7/9/09.
This tool has not been validated. NCCN defined periods of increased vulnerability for distress:

## NCCN Defined Periods of Increased Vulnerability for Distress:

- Symptom suspicion
- Work up/staging
- Diagnosis
- Awaiting treatment
- Change in treatment modality
- End of treatment
- Discharge from hospital following treatment
- Stresses of survivorship
- Medical follow-up and surveillance
- Treatment failure
- Recurrence/progression
- Advanced cancer
- End of life

**References:**


Adler, N.E., & Page, A.E. (2008). *Cancer care for the whole patient: Meeting psychosocial health needs.* Washington, D.C.: National Academies Press.

Epstein, R.M., & Street, R.L. (2007). *Patient centered communication in cancer care: Promoting healing and reducing suffering.* (NIH Publication No. 07-6225). Bethesda, MD: National Cancer Institute.

National Comprehensive Cancer Network. (2009). *NCCN clinical practice guidelines in oncologyTM: Distress management v2.2009.* Fort Washington, PA: Author.

# NCCCP Cancer Palliative Care Assessment Tool

This tool allows community cancer centers to self-assess and improve their palliative care services. Palliative care programs in some health care settings may utilize "supportive care" or "symptom management" in their titles.

## NCCCP Cancer Palliative Care Assessment Tool

Purpose: The Palliative Care Assessment Tool is designed for community cancer programs to use as a self-assessment tool in evaluating and improving their palliative care services. Palliative care programs in some health care settings may utilize "supportive care" or "symptom management" in their titles.

| Category | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| Patient Symptom Assessment at Each Physician/Care Provider Encounter:<br>■ Pain<br>■ Fatigue<br>■ Mobility / Independence<br>■ Constipation<br>■ Diarrhea<br>■ Nausea / Vomiting<br>■ Lack of Appetite<br>■ Shortness of Breath<br>■ Sexual Dysfunction<br>■ Distress- (See psychosocial matrix)<br>● (Additional symptoms as appropriate for disease site) | None documented | Inconsistent documentation of symptoms | Consistent documentation, variable measurement tools | Consistent documentation with consistent tools | 4 plus sequential comparisons available |
| Palliative Care/Supportive Care (PC/SC) services are provided across the continuum of patient care settings | None available | Consultative inpatient PC/SC program (physician, APN or NP-led) | Level 2 plus 24/7 Availability of Consultative PC/SC outpatient multi-disciplinary team | Level 3 and Outpatient PC/SC continuity clinic care services available | Palliative Care/Supportive Care services regardless of patient location |
| Patient Identification/Case Finding for Palliative Care Services | Only end-of-life patients are referred | Patients with advanced stage cancer with severe symptoms | Patients at any stage cancer with severe symptoms | Patients referred at any stage, regardless of symptoms | Referral for any diagnosis stage as well as survivors with concerns/symptoms |
| Patient Identification/Case Finding for Hospice Care Services | Hospice option presented when death is imminent | | Hospice option presented to all patients with stage IV disease | | Hospice presented as an option to all patients and families when death within a year would not be surprising and is reintroduced as an option as the patient declines |
| Patient Access/Referral | Single practice or specialty refers | | Multiple physician referral sources | | Referrals from patient, family or non-MD staff permitted |
| Assessment of Potential Barriers to Palliative Care | No specific assessment utilized | | Cultural, socioeconomic, geographic assessment for each patient | | Resources available to overcome patient disadvantages and barriers |

| Category | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| Quality and Impact Measurements<br>Measures are defined, routinely monitored and improvements documented. Includes monitoring data for the following categories: 2<br>■ Pain and symptom control<br>■ Program operational measures (e.g. number and type of referrals, number of advanced directives, hospice referrals, etc.)<br>■ Patient, family, and healthcare provider satisfaction<br>■ Financial impact and resource utilization (e.g. hospital and/or ICU length of stay, pharmacy costs before and after consultation, etc.) | None | Pain and symptom control outcome data measured and monitored | Level two plus one additional quality/ impact outcome measure category | Level three plus one additional quality/impact outcome measure category | Monitoring all 4 quality outcome/ impact measure categories |
| Palliative Care Program Leadership<br>Hospice care and specialized palliative care professionals should be appropriately trained, credentialed and/or certified in their area of expertise[1] | None | Leader has documented annual attendance at Hospice and Palliative Care CME/CEU programs | EPEC / ELNEC curriculum trained physician or nurse clinical leader | Physician leader is board eligible for American Board of Hospice and Palliative Medicine (ABHPM) | Physician leader is ABHPM certified. |
| Staff Competencies Education/ Training/Awareness<br>Provide adequate training and clinical support to assure that professional staff are confident in their ability to provide palliative care for patients.[1] | None | Education program offered annually | Annual education and PC/SC training provided during new staff orientation for IP and OP oncology settings | Level 3 and Annual staff competency evaluations for IP and OP oncology settings | Ongoing education, training, and assessment for all levels of staff for IP and OP oncology settings. |
| Patient Education and Self-Management<br>Enable patients to make informed decisions about their care by educating them on the process of their disease, prognosis, and the benefits and burdens of potential interventions.[1] | No educational materials or resources provided | | Print or web-site resources are provided specific to disease site | | Customized and individualized resources are provided |
| Advanced Care Planning<br>Formulate, utilize and regularly review a timely care plan based on a comprehensive interdisciplinary assessment of the values, preferences, goals and needs of the patient and family and, to the extent that existing privacy laws permit, ensure that the plan is broadly disseminated, both internally and externally, to all professionals involved in the patient's care.[1] | Not addressed | Advanced Directives requested and copy in patient chart. Conduct community education programs on advanced care planning | Care plan discussion with patient occurs at hospital admission or initial visit | Conduct and document goal of care conferences with patient and family and entire health care team | Care plan is reviewed and discussed with patient and family when patient condition changes or at regular intervals (at least annually)<br>All patients have advanced directives |
| Advanced Care Plan Dissemination<br>Make advance directives and surrogacy designations available across care settings while protecting patient privacy and adherence to HIPAA regulations, e.g., by Internet-based registries or electronic personal health records.[1] | No specific mechanism | | Advance directives and surrogacy designations are shared across hospital settings | Advance directives and surrogacy designations are shared across hospital settings and physician offices | Advance directives and surrogacy designations are readily available and follow the patient across all health settings |

| Category | Level 1 | Level 2 | Level 3 | Level 4 | Level 5 |
|---|---|---|---|---|---|
| Rehabilitation Services | None available | PT/OT/Speech services | 2 and inpatient rehabilitation care available | 3 and outpatient rehabilitation physician consultation available | 4 and cancer program-associated rehabilitation physician |
| Psychosocial Interventions Assess and manage psychological<br>reactions of patients and families to address emotional and functional impairment and loss, including stress, anticipatory grief and coping, in a regular ongoing fashion.[1] | None provided | | Available to inpatients | | Readily available to both inpatients and outpatients |
| Spiritual Care Program | No specific assessment or resources | Chaplain service available for all patients and families | Spiritual assessment for all patients | | Spiritual resources available as patient needs and requests around the clock |
| Palliative Care Staff Support<br>Examples include formal debriefing and/or case conferences for difficult cases, Schwartz Center Rounds, team support group sessions, and educational needs-assessment-driven programs[1] | None | Bi-annual | Annual | Quarterly | Monthly |


1. Policies and Tools for Hospital Palliative Care Programs: A Crosswalk of National Quality Forum Preferred Practices. Center to Advance Palliative Care. http://www.capc.org/support-from-capc/capc_publications/nqf-crosswalk.pdf
2. Center to Advance Palliative Care. http://www.capc.org/building-a-hospital-based-palliative-care-program/measuring-quality-and-impact/index_html#2


The NCCCP Cancer Palliative Care Assessment Tool Version 2.0 was approved by the program's Executive Subcommittee May 14, 2009.

**This tool has not been validated.**

# NCCCP Cancer Medical Staff Conditions of Participation

This document outlines the 'conditions of participation' recommendations to support the goals of the NCCCP. The tool addresses the core elements of the requirements—including participation in clinical trials and quality of care initiatives—board certification, and acceptance of uninsured patients for treatment.

## Recommendations

Cancer Center Medical Staff *Conditions of Participation* NCCCP Pilot Program

| Category | Criteria | Requirement | Suggested Metrics |
|---|---|---|---|
| Professional affiliations | | | |
| | Active member of hospital medical staff | Required | Hospital to confirm |
| | Board eligible, certification, and re-certification as required | Required | Provide documentation |
| | Membership in oncologic societies, if available for specialty | Required | Provide documentation |
| | Leadership role and/or participation in local, state, national community cancer activities | Strongly encouraged | Must participate in at least one activity yearly |
| Cancer expertise/ Continuing education | | | |
| | Attendance at national and local oncology conferences (e.g. ASCO, ASTRO, AACR) with oncology CME credits | Strongly encouraged | 20 CME credits every 2 years in oncology related topics from national and local conferences combined. |
| | Dedicated commitment to a specific disease area and demonstration of an appropriate volume which allows the physician to provide care for patients with good outcomes | Strongly encouraged | Completion of Fellowship training in medical oncology/ surgical/ radiation oncology, or a General Surgery, Pulmonology, Gynecology, Pathology, Imaging, Neurology practice focused in one or two disease sites. |
| | Publications/presentations | Strongly encouraged | Hospital to track |
| Research/Clinical Trials | | | |
| | Participation in clinical trials and/or secondary or team credit for accrual coordination, referrals or support for trials (surgeons, urologists, radiation oncologists). | Required | Must place/refer/support patients on clinical trials (confirmation provided by cancer center clinical trials /research coordinator) |
| | Completion of the Human Participants Protection Education for Research Teams online course (required by NIH to be an investigator for Cooperative group or NCI studies). | Required | Provide documentation of education |
| | Involvement in national oncology research activities such as: CALGB, ECOG, SWOG, RTOG, NSABP, GOG | Strongly encouraged | Active participation and/or membership with at least one of these organizations |
| Cancer Practice Commitments | | All criteria listed will be part of acceptance of conditions of participation agreement/ obligations. | |

| Category | Criteria | Requirement | Suggested Metrics |
|---|---|---|---|
| | Commit to a philosophy of cancer care which includes:<br>■ Discuss all appropriate treatment options with patients<br>■ Communication with primary care or referring physician throughout diagnosis and treatment, provide timely follow–up communication regarding patient recommendations, treatment status, and outcomes (e.g. within one week)<br>■ A willingness to provide timely verbal consults to cancer center and hospital physicians<br>■ A willingness to provide second opinions at request of patients or referring physicians (e.g. same day)<br>■ A commitment to the provision of timely patient return and coordination of follow up care<br>■ Embraces multidisciplinary care, collaborating prospectively with other members of the patient's care team and involving the patient/family as partner.<br>■ Participation with navigators/care managers as available and when appropriate<br>■ Provide the treatment plan and summary as developed by the cancer center based on recommendations from the NCI NCCCP Program. | | |
| Cancer Program Obligations | | All criteria below to be part of acceptance of conditions of participation agreement/ obligations. | |
| | Commitment to being part of a strong oncology practice group committed to providing vision, oversight, and plans for growth and research support for the NCCCP program. | | |
| | Follow evidence-based guidelines such as: ASCO/NCCN or similar guidelines offered at the cancer center. | | |
| | Provide data and clinical information to support cancer center patient care and Performance Improvement efforts including sharing patient office practice data with cancer research office and/or registry as needed for quality data. | | |
| | Participate in multi-disciplinary conferences, site specific tumor boards, and/or specific tumor conferences as appropriate for the cancer center | | Participate in at least 60% of local cancer center site specific tumor conferences. |
| | Commitment to follow professional societies' (ASCO, NSGC, ASHG) recommendations on cancer genetics that include evaluation by appropriately trained professionals in genetic counseling, screening, and testing. | | |
| | Participate in at least one Performance Improvement activity annually | | |
| | Provide cancer registry with timely information | | |
| | Conduct oncology educational sessions for staff, primary care physicians as appropriate | | |
| | Provide care for the uninsured/underserved per hospital specific policy for the NCCCP program (e.g. agree to accept on a fair and proportional basis with other participating physicians, any patients referred through the cancer center) | | |
| | Support cancer screening efforts | | |

# NCCCP Physician Director Role

This provides a description of the recommended responsibilities for a community cancer center physician director, including physician qualification requirements and program oversight responsibilities for supporting active participation in the NCCCP network requirements/program components.

## NCI Community Cancer Centers Program (NCCCP)
## Recommended Role Responsibilities

**Physician Director**

**(FINAL 9-08)**

### Overview of Responsibilities

The Physician Director for the NCCCP Pilot Program will have a broad scope of authority and accountability to oversee all aspects of the cancer program and shall dedicate most of his or her time to the program including patient care responsibilities. He/she will have reporting relationships and authority within the organization which enable them to be accountable for the cancer program and the related NCCCP program components in support of the quality of comprehensive cancer care and NCCCP program goals. He/she will provide leadership for the vision and strategic plan for the NCCCP program and will be an active participant in the NCCCP network. Specific responsibilities shall include:

- **Patient Care**
  - Coordination of program components which support the comprehensive care of cancer patients in an NCCCP pilot program:
    - Multi-disciplinary Care
    - Patient Navigation
    - Survivorship and Palliative Care
    - Genetic Counseling and Molecular/Gene Testing
  - Collaboration with key hospital departments and other organizational entities to insure seamless and coordinated care for cancer patients (e.g. Nursing, Operating Room, Imaging, Laboratory/Pathology, Information Technology) and the necessary linkages for all NCCCP program components (e.g. CaBIG™, EHRs, NCI Biospecimen Best Practices, hospice, NCI designated Cancer Centers )
- **Quality of Care**
  - Oversight of performance improvement efforts as related to clinical outcomes and patient quality of life
  - Oversight of implementation of evidence-based guidelines such as NCCN, ASCO.
  - Oversight of cancer–related accreditations (Commission on Cancer, ASCO QOPI, Breast Center Accreditation, etc.)
  - Coordination or oversight of the tumor registry to insure ability to track patient outcomes, practice patterns and quality of care.
- **Cancer Center Medical Staff Engagement**
  - Collaboration with medical staff of the cancer program, often private practices, to insure a dedicated oncology practice leadership group committed to the goals and vision of the NCCCP pilot program.
  - Recruitment and retention of medical staff, private practices and employed physicians, to support the cancer center.
  - Collaboration with medical specialties to support the cancer program.
  - Oversight of the development and implementation of medical staff conditions of participation to support quality patient care, research, and community outreach goals.
  - Oversight of efforts to increase physician participation in clinical trials
  - Oversight of peer review/performance improvement activities for the medical staff of the cancer program.
  - Promotion of EHR linkages with cancer center medical staff to support improved quality and coordination of patient care for cancer center patients.
  - Oversight of cancer education programs, seminars and conferences for medical staff

- **Clinical Cancer Research**
  - Oversight of cancer clinical trials ensuring IRB and study compliance
  - Coordination and oversight of cancer research which could include translational, pharmaceutical, psycho-social, and disparities research
  - Coordination of linkages with NCI-designated Cancer Centers
  - Promotion of linkages with CCOPs, NCI Cooperative Groups, Community Networks programs and other NCI programs as applicable
  - Promotion of academic relationships in support of the teaching and research goals of the cancer program
- **Community Relationships**
  - Development/enhancement of relationships with community organizations which support underserved patients and which offer programs and services to support cancer patients (e.g. State Cancer Control Plans, American Cancer Society, Leukemia & Lymphoma Society, Wellness Community). Participation in and support of ongoing staff linkages with these organizations.
  - Oversight of patient and community cancer education and screening programs with a special focus on serving disparate populations.
  - Leadership in fundraising and grant writing to support the cancer center's programs and services
  - Promotion of cancer program marketing and public relations efforts.

## Physician Director Qualifications

- M.D. or D.O.
- Board certification in a cancer or cancer-related specialty
- Extensive experience in clinical oncology and patient care
- Demonstrated clinical administrative and leadership skills, including grantsmanship
- Demonstrated experience in medical staff recruitment/development
- Demonstrated experience and involvement in cancer program-related community activities.

# NCCCP Biospecimens Gap and Fill Assessment Tool (GAFAT) and Biospecimen Percentage Implementation Tool (BPIT)

The GAFAT was used by NCCCP sites to identify gaps in their biospecimen programs and solutions to fill those gaps. It addressed competencies such as biospecimen consent; annotation, collection, storage, and distribution; biosafety; quality assurance; and responsible custodianship. The GAFAT helped sites evaluate their capabilities for proper handling of biospecimens and showed capacity for supporting and participating in clinical trials with a tissue collection component. Many NCCCP sites also used the BPIT, an Excel spreadsheet, to track quarterly progress for implementing the solutions or "fills" identified on the GAFAT.

## NCI Biomedical Information Network Self Assessment Worksheet with: NCCCP Biospecimens Subcommittee Gap and Fill Assessment Tool/Biospecimen Practices Implementation Tool (GAFAT-BPIT)

This comprehensive assessment tool is based on NCI's *Best Practices for Biospecimen Resources* (http://biospecimens.cancer.gov/practices/2010bp.asp) and is used as the basis for this site-specific baseline (Gap And Fill Analysis Tool, GAFAT) and quarterly implementation tool (Best Practices Implementation Tool, BPIT). Each site should answer the questions for ALL patient tumor resections—not just for research purposes (definition of biospecimen for this tool = ALL patient tumor resections). You should assume that you will be either storing biospecimens in a biospecimen resource (biorepository, biobank) at your facility OR that you will be sending biospecimens to another facility, and that the biospecimens will be used for molecular testing and/or research at some point in their lifetime (appropriate biospecimen custodianship).

The questions are sequentially arranged and correspond to the sequence in the Best Practices. This process and electronic document will create your initial site-specific baseline data (GAFAT due within 6 months of receipt: March 1 to August 30—due on or before September 1, 2011) and be used for your quarterly reports to document your implementation of the *Best Practices* (quarterly update of BPIT).

### The GAFAT

Complete one question before moving on to another question. Use the pull down lists for each question to select the gaps and fills that you identify. Make sure you are using a Windows-based PC and **make sure your Excel macros are activated**. Click the cell and a range selection arrow will pop up in the right lower corner next to the cell. Click the arrow and then click your answer(s) from the pull-down menu. If more than one Gap or Fill is needed, repeat the process. If your gap or fill is not included in the list (selections identified in the pilot program), use the free text field, BUT use only if your comment is absolutely novel and cannot be included in one of the available choices. When the Gap(s) and Fill(s) are identified for that question, choose 100 from the pull down list in the "% Comp" column. If you have not completed your Gaps and Fills, choose "0" in the first column, "% Completion".

### The BPIT

Choose 25, 50, 75, or 100 from the pull down list in the BPIT "% Comp" column depending upon your estimate of the percentage of the gaps that have been filled (implemented) for each question. The beginning default is "0". You do not have to choose "0"—you can leave it blank.

| | | Gap and Fill Analysis Tool Baseline (GAFAT) and Best Practices Implementation Tool (BPIT, quarterly reportable) | | | | | BPIT |
|---|---|---|---|---|---|---|---|
| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
| B.1.1.1 | Have you defined and documented your organizational structure before your biospecimen resource planning and development? | | | | | | |
| B.1.1.2.a | Have you publicly displayed your current organizational chart within the biospecimen resource? | | | | | | |
| B.1.1.2.b | Do you discuss your current biospecimen resource organizational and institutional governance structures with every new employee? | | | | | | |
| B.1.2.1 | Have you defined the appropriate personnel and created the teams listed in this section that are appropriate to your institution? | | | | | | |
| B.1.2.2.a | Have you formed your Scientific Advisory Committee? | | | | | | |
| B.1.2.2.b | Have you formed your Tissue Utilization Committee? | | | | | | |
| B.1.2.3 | Have you included as stakeholders and consultants the associated institutional offices and adjunct committees as described in this section? | | | | | | |
| B.1.3.1.a | Have you defined and documented that your biospecimen resource's policies are in alignment with your biospecimen resource's mission, scope, and operational objectives? | | | | | | |
| B.1.3.1.b | Have you formally vetted and approved with documentation the policies defined in this section? | | | | | | |
| B.1.3.2.a | Has your biospecimen resource manager(s) familiarized her/himself with the Best Practices as described in this section? | | | | | | |
| B.1.3.2.b | Have your biospecimen resource staff and adjunct teams been oriented to the current Best Practices sufficiently so that they can follow them appropriately? | | | | | | |
| B.1.3.2.c | Have the Best Practices and current relevant standards been incorporated into your biospecimen resource policies, SOPs, and procedures using evidence-based practices when available? | | | | | | |
| B.1.3.3.a | Have you integrated your business planning into all aspects of operations, biospecimen resource management, and evaluation? | | | | | | |
| B.1.3.3.b | Have you established a documented annual business plan according to the recommendations in this section? | | | | | | |
| B.1.3.3.c | Does your business plan include a formal continuity plan that addresses all possible operational disruptions including disaster planning? | | | | | | |
| B.1.3.3.d | If your biospecimen resource functions as a service center, does your business plan address issues related to service and revenue generation? | | | | | | |
| B.1.4.a | Have you considered and documented the space requirements for the areas listed in this section? | | | | | | |
| B.1.4.b | In your biospecimen resource design and implementation, have you evaluated the options and opportunities for environmentally friendly infrastructure as described in this section? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| B.1.5.1 | Have you considered the recommendations concerning equipment selection and maintenance in this section? | | | | | | |
| B.1.5.2 | Are you familiar with the purchasing and overall procurement process in your institution as described in this section? | | | | | | |
| B.1.5.3 | Have you developed a proactive project management plan with the sections described in this section? | | | | | | |
| B.1.5.4.a | Do you assess specimen utilization in a timely and efficient manner? | | | | | | |
| B.1.5.4.b | Do you document and track utilization in conjunction with the biospecimen resource inventory management system? | | | | | | |
| B.1.5.4.c | Do you share information about their biospecimens with the external (donor) community through a biospecimen management information system or other means? | | | | | | |
| B.1.6.1 | Are you prepared for and do you do self-audits to evaluate both the quality and the problem areas of your biospecimen resource, including monitoring end-user support for your clinical biobanking efforts? | | | | | | |
| B.1.6.2 | Do you do strategic and long-range planning including the setting of benchmarks? | | | | | | |
| B.1.6.3 | Do you quantify and document your performance including utilization review and the assessment of the continuing research needs of the biospecimen resource? | | | | | | |
| B.1.6.4 | Do you do a formal analysis of your biospecimen resource's scientific impact and document it? | | | | | | |
| B.2.1.1.1 | Do make an effort to collect and record the information about the patient's (donor's) physiological variables as recommended in this section? | | | | | | |
| B.2.1.1.2.a | Do you collect and record the methods used to remove, collect, and preserve your biospecimens in order to decrease the variability and improve the quality of your biospecimens as recommended in this section? | | | | | | |
| B.2.1.1.2.b | Do you have a plan in place, prior to the removal of a biospecimen, that allows the appropriate annotation of the biospecimen as recommended in this section? | | | | | | |
| B.2.1.1.3 | Do you optimize and document the handling and processing of your biospecimens to insure the highest quality of the biospecimens as recommended in this section? | | | | | | |
| B.2.1.2 | Do you minimize errors in assay reproducibility by implementing and documenting the recommendations made in this section? | | | | | | |
| B.2.2 | Are the biospecimens you collect appropriate and feasible for the clinical setting as well as being appropriate for the downstream applications anticipated for the biospecimens? | | | | | | |
| B.2.3 | Do you, when possible, characterize and document the reference range for the analyze of interest? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| B.2.4.a | Are your standard operating procedures (SOPs) for analyte testing reproducible with standard reference materials using a range of anticipated assay values where possible? | | | | | | |
| B.2.4.b | When you analyze a specific biomolecule, do you perform and document the analyses that optimize the storage and handling conditions of the biospecimen(s) for that biomolecule? | | | | | | |
| B.2.5 | Do you incorporate into your research program, “proof of performance” tests as recommended in this section? | | | | | | |
| B.2.6.1 | Do you consistently apply, and document the consistent application, the SOPs used in preparing and storing biospecimens as described in this section? | | | | | | |
| B.2.6.2.a | Do you store frozen biospecimens in a stabilized state without unnecessary freeze-thaw cycles as described in this section? | | | | | | |
| B.2.6.2.b | Do you follow consistent and validated SOPs for thawing and re-freezing biospecimens? | | | | | | |
| B.2.6.3 | Are your biospecimen storage containers and labels appropriate for the biospecimens, and stable under the planned storage conditions, especially when using liquid nitrogen storage? | | | | | | |
| B.2.6.4 | Does each stored biospecimen have a unique identifier or combination of identifiers that are firmly attached to the storage container, clearly and legibly marked, and able to endure the storage conditions? | | | | | | |
| B.2.6.5 | Does your storage equipment have automated alarm systems that continuously monitor and warn biospecimen resource personnel when equipment failure occurs? | | | | | | |
| B.2.6.6 | Are your biospecimens stored in a secure location with limited access only by authorized personnel? | | | | | | |
| B.2.7 | Are your biospecimens retrieved from storage according to biospecimen resource SOPs that safeguard sample quality? | | | | | | |
| B.2.8.1.1 | Are your frozen biospecimens shipped according to biospecimen resource SOPs that safeguard sample quality, including a temperature measuring/recording device within the shipping container that indicates the minimum and/or maximum temperature that occurred during shipping? | | | | | | |
| B.2.8.1.2.a | Are your paraffin-embedded blocks shipped according to biospecimen resource SOPs that safeguard sample quality, including a temperature measuring/recording device within the shipping container that indicates the minimum and/or maximum temperature that occurred during shipping? | | | | | | |
| B.2.8.1.2.b | Are your fixed, but not paraffin-embedded, biospecimens shipped according to biospecimen resource SOPs that safeguard sample quality, including a temperature measuring/recording device within the shipping container that indicates the minimum and/or maximum temperature that occurred during shipping? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| B.2.8.1.3.a | Do you place the number of biospecimens in a shipping container that are appropriate for the biospecimen and the container? | | | | | | |
| B.2.8.1.3.b | Do you perform a test shipment before shipping extremely valuable biospecimens as described in this section? | | | | | | |
| B.2.8.2.1 | When you plan the shipment of a biospecimen, do you create the required Material Transfer Agreement (MTA) and obtain the requisition from the biospecimen resource? | | | | | | |
| B.2.8.2.2.a | Do you notify the recipient before shipping to confirm that someone will be present to accept the package and properly store the biospecimen? | | | | | | |
| B.2.8.2.2.b | Does standardized paperwork (shipping manifest) accompany your shipments as well as an electronic version of the shipping manifest being sent to the recipient? | | | | | | |
| B.2.8.2.2.c | Upon receipt of your shipment, do the receiving personnel review the shipped biospecimen and manifest for discrepancies and document and resolve any discrepancies identified? | | | | | | |
| B.2.8.3.1 | When shipping biospecimens internationally, do you consult the ISBER Best Practices and International Air Transport Association (IATA) regulations and follow their recommendations and requirements? | | | | | | |
| B.2.8.3.2 | Do you consult the Occupational Safety and Health Administration (OSHA) regulations on toxic and hazardous substances (29 CFR 1910 Subpart Z) to determine whether a substance requires a biohazard label? | | | | | | |
| B.2.8.4 | Are your biospecimen resource personnel initially trained, and periodically retrained, on the regulations for shipping biospecimens internationally? | | | | | | |
| B.3.1 | Does your biospecimen resource carry out its functions within a quality management system (QMS) that contains formalized quality assurance/ quality control (QA/QC) policies and written SOPs? | | | | | | |
| B.3.2.a | Does your biospecimen resource's quality management system implement and audit the staff proficiency following the recommendations in this section? | | | | | | |
| B.3.2.b | Does your biospecimen resource's quality management system implement and audit the facility infrastructure following the recommendations in this section? | | | | | | |
| B.3.2.c | Does your biospecimen resource's quality management system implement and audit the biospecimen control and documentation following the recommendations in this section? | | | | | | |
| B.3.2.d | Does your biospecimen resource's quality management system implement and audit the record keeping and document control following the recommendations in this section? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| B.3.2.e | Does your biospecimen resource's quality management system implement and audit the scheduled and unscheduled internal audit programs and their policies following the recommendations in this section? | | | | | | |
| B.3.3.1 | Does your manual of standard operating procedures (SOPs) minimally include all twelve (12) areas recommended and described in this section? | | | | | | |
| B.3.3.2.a | Does the biospecimen resource director and/or the individual responsible for the QA/QC program review and approve all SOPs and associated process validation studies prior to implementation of the biospecimen resource? | | | | | | |
| B.3.3.2.b | Does the biospecimen resource director and/or the individual responsible for the QA/QC program evaluate the compliance and effectiveness of the QA/QC measures on a routine basis? | | | | | | |
| B.3.3.3.a | Does your biospecimen resource have a document control program and policies for governing, modifying, and/or revising SOPs? | | | | | | |
| B.3.3.3.b | Does the biospecimen resource director review all the SOPs at least every two (2) years and whenever significant modifications are made and document this review? | | | | | | |
| B.3.3.4.a | Are current copies of the SOPs manual stored in designated locations and available, either in hard copy or electronically, to the staff at all times? | | | | | | |
| B.3.3.4.b | Do the staff review new and revised SOPs and is each individual's review documented? | | | | | | |
| B.4.1.1 | Does your biospecimen resource use and monitor biohazard precautions/work practices similar to those used in clinical laboratories and clinical settings as described in this section? | | | | | | |
| B.4.1.2.a | Do you have clear policies regarding the inclusion or exclusion of high-risk biospecimens as described in this section? | | | | | | |
| B.4.1.2.b | Have your biospecimen resource personnel been trained, and the individual training documented, to perform biospecimen risk assessments and determine the appropriate levels of containment? | | | | | | |
| B.4.1.3 | Have you established policies consistent with CDC's "Select Agents and Toxins" regulations as described in this section? | | | | | | |
| B.4.2.1 | Have you developed or are developing your overall biohazard safety and training program and were/are the governmental and accrediting agencies requirements incorporated as described in this section? | | | | | | |
| B.4.2.2 | Do you frequently identify biospecimen resource activities that may have safety issues and implement suitable controls? | | | | | | |
| B.4.2.3 | Is your biohazard safety and training program reviewed on a periodic basis including review of any relied upon updated governmental and/or accrediting biosafety guidelines? | | | | | | |
| B.4.2.4 | Do you document the biohazard precautions/work practice training and competence on an individual basis? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| B.4.2.5 | Do you have a SOP regarding the documentation of, and the treatment of, all incidents within your biospecimen resource where personnel are exposed to biohazards and/or are potentially infected? | | | | | | |
| B.4.3 | Does your biospecimen resource follow strict general safety regulations and procedures regarding chemical, electrical, fire, physical, and radiological safety? | | | | | | |
| B.5.1.1 | Do your data collection activities conform to FDA requirements, if and where applicable, so that the data may be cited and/or used in Investigational New Drug and Investigational Device Exemption applications as described in this section? | | | | | | |
| B.5.2.1 | When appropriate, do you collect relevant clinical data associated with a biospecimen in accordance with relevant human subject and privacy regulations? | | | | | | |
| B.5.2.2 | Do you employ a uniform, nonredundant vocabulary for clinical data as described in this section? | | | | | | |
| B.5.2.3 | Does your biospecimen resource comply with applicable privacy statutes and regulations and human subjects protection regulations governing the acquisition of biospecimens and associated clinical data as described in this section? | | | | | | |
| B.5.2.4 | Do you track researcher's requests for specimens with specific clinical data to guide the refinement of clinical data collection as described in this section? | | | | | | |
| B.5.3.1 | When the study requirements dictate, do you collect and store longitudinal data following applicable informed consent and authorization requirements as described in this section? | | | | | | |
| B.5.3.2 | Do you use a Minimal Clinical Data Set for linking certain clinical data to a biospecimen such as demographic data, lifestyle factors, environmental and occupational exposures, cancer history, structured pathology data, additional diagnostic studies, information on initial staging procedure, treatment data, and any other data relevant to tracking a research participant's clinical outcome as described in this section? | | | | | | |
| B.5.3.3 | If you develop databases for longitudinal studies, is the coded data associated with a biospecimen securely linked to the donor so that longitudinal data can be added to the record if permitted by law and by the donor's consent/authorization documents? | | | | | | |
| B.5.3.4 | Are your policies and protocols optimized to facilitate access to uniform longitudinal data as appropriate, while protecting the donor's privacy and confidentiality? | | | | | | |
| B.5.3.5 | Do you ensure that dedicated and trained personnel curate your longitudinal clinical data with validation of the collection process and QA/QC? | | | | | | |
| B.5.4.1 | Does your informatics system track all aspects of biospecimen collection, processing, and distribution to support high-quality annotation of the biospecimen, its characteristics, and other associated data (see Section B.6 for details)? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| B.6 | Have you read this section and understand how data management, inventory control, and biospecimen tracking need to be implemented in your biospecimen resource as described in this section? | | | | | | |
| B.6.1.1 | Is your biospecimen resource informatics system focused on recording data types as described in Section B.5., including the inventory functions listed in this section? | | | | | | |
| B.6.1.2 | Does your biospecimen resource informatics system have the capability of linking labels on the physical biospecimen container to other information regarding that biospecimen in the system? | | | | | | |
| B.6.1.3 | Does your biospecimen resource informatics system track clinical data associated with a biospecimen and/or link biospecimen data with external sources of clinical data, where applicable? | | | | | | |
| B.6.1.4 | Does your biospecimen resource informatics system monitor and report on biospecimen quality in terms of the scientific best practices defined in Section B.2.? | | | | | | |
| B.6.1.5 | Does your biospecimen resource informatics system provide vital system statistics and audit logs of all access to protected health information in the database? | | | | | | |
| B.6.2.1 | Does your informatics system record the origin of each physical part created by extraction, division into aliquots, or other physical division of a biospecimen? | | | | | | |
| B.6.2.2 | Does each biospecimen have a globally unique identifier or combination of identifiers assigned (number or barcode [preferable]) as described in this section? | | | | | | |
| B.6.2.3 | Does your biospecimen resource informatics system track biospecimen processing, storage, distribution and return of biospecimens and their derived information from clients and associate them with the appropriate information derived from the original biospecimen? | | | | | | |
| B.6.2.4 | Does your biospecimen resource informatics system update the database each time a biospecimen or sample is moved within or out of the biospecimen resource by tracking its location? | | | | | | |
| B.6.3.1 | Does your biospecimen resource informatics system have the interoperability to enable integration with local and with other cross-site systems? | | | | | | |
| B.6.3.2 | Does your biospecimen resource informatics system have the interoperability to enable integration with other clinical data systems such as the anatomic and clinical laboratory information system(s), and cancer registries? | | | | | | |
| B.6.3.3 | Does your biospecimen resource informatics system support a minimum set of common queries that can be submitted to all systems using common data elements (CDEs)? | | | | | | |
| B.6.3.4 | Is your biospecimen resource informatics system caBIG compatible? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| B.6.3.5 | Can your biospecimen resource informatics system utilize data elements from a common metadata repository, such as the Cancer Data Standards Repository? | | | | | | |
| B.6.3.6 | Can your biospecimen resource informatics management system share appropriate, deidentified biospecimen data to users at remote locations for multiple purposes including satisfying reporting and regulatory requirements as well as searching for potential biospecimens for a proposed scientific study? | | | | | | |
| B.6.4.1 | Is your biospecimen resource informatics system based on “use cases” and other techniques that capture needs for managing biospecimen resources and implemented via appropriate SOPs? | | | | | | |
| B.6.4.2 | Does your biospecimen resource informatics system use software and system development methodology for initial development and subsequent revisions ? | | | | | | |
| B.6.4.3 | Does your biospecimen resource software and system engineering organizations meet at least Capability Maturity Model Integration [CMMI] Level 3? | | | | | | |
| B.6.5.1 | Have you identified the minimum set of requirements for software needs and storage needs to address current and estimated future needs? | | | | | | |
| B.6.5.2 | Have you used the criteria you defined in Section B.6.5.1 to judge mature open-source and commercially available systems as described in this section? | | | | | | |
| B.6.6.1 | Does your biospecimen resource informatics system have an operational infrastructure to support operation 24 hours a day, 7 days a week? | | | | | | |
| B.6.6.2 | Does your biospecimen resource informatics system have processes in place to cope with system downtimes and disaster recovery? | | | | | | |
| B.6.6.3 | Is your biospecimen resource informatics system periodically evaluated to ensure that the system is fulfilling the criteria advised in the Best Practices and the latest needs of the Biospecimen resource? | | | | | | |
| B.6.6.4 | Does your biospecimen resource informatics system have the capability to routinely monitor and validate the accuracy of the tools you use to extract structured information from free-text data, such as surgical pathology reports? | | | | | | |
| B.6.6.5 | Are all of your biospecimen resource informatics system databases at an individual institution in a secure site and monitored by the institution as described in this section? | | | | | | |
| B.6.7.1.a | Does your biospecimen resource informatics system meet relevant State and Federal requirements that encourage the use of electronic signature where appropriate? | | | | | | |
| B.6.7.1.b | Does your biospecimen resource informatics system meet relevant State and Federal requirements that encourage the use of information technology accessibility standards for handicapped persons where appropriate? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| B.6.7.2 | Do you refer to the National Institute of Standards and Technology Special Publication 800-30 “Risk Management Guide for Information Technology Systems” to determine the appropriate level of security for your informatics systems? | | | | | | |
| C.1 | Does your biosepcimen resource understand the scope of the Ethical, Legal, and Policy section of the Best Practices: Principles of Responsible Custodianship as described in this section? | | | | | | |
| C.1.1 | Does your biospecimen resource address formal and continuing responsibility for custodianship of collected biospecimens and associated data as part of their protocols, including the issues described in this secction that should be addressed in the governance plan? | | | | | | |
| C.1.2.a | Does your biospecimen resource have a legacy or contingency plan as part of the overall governance plan as described in this section? | | | | | | |
| C.1.2.b | Does your biospecimen resource’s legacy or contingency plan address the handling and disposition of biospecimens and associated data at one or more of the points described in this section? | | | | | | |
| C.1.3.a | Has your biospecimen resource established and documented transparent policies governing the retention of biospecimens and data? | | | | | | |
| C.1.3.b | Do your biospecimen resource’s usage agreements, such as MTAs, specify the retention policies of the recipient investigator and other considerations related to specimen retention as escribed in this section? | | | | | | |
| C.1.4 | Does your biospecimen resource, as a responsible custodian, manage existing or potential conflict of interests (COIs) and adhere to regulations regarding COIs at 42 CFR Part 50 Subpart F as described in this section as well as other applicable regulations and policies. (Also see Section C.6, Conflicts of Interest.)? | | | | | | |
| C.1.5.b | Does your biospecimen resource implement transparent policies for maintaining the confidentiality and security of the biospecimens and associated clinical data, if applicable, as described in this section? | | | | | | |
| C.1.6.a | Does your biospecimen resource, where practicable, share the general information described in this section with human research participants via their web site or alternate mechanism? | | | | | | |
| C.1.6.b | Does your biospecimen resource include the information and/or the corresponding Web link described in Section C.1.6.a. above, in the informed consent supplementary material; e.g., a brochure? | | | | | | |
| C.1.7 | Does your biospecimen resource make public (e.g., on a web site) a summary of its governance plan and/or an accompanying graphic of its organization? | | | | | | |
| C.2 | Do you understand the scope of the informed consent for biospecimen donation as described in this section? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| C.2.1.1 | Do you track whether appropriate informed consent is present (if applicable) or the reason why informed consent is not necessary? | | | | | | |
| C.2.1.2 | Have you satisfied the Office for Human Research Protections (OHRP) guidance on the regulatory requirements that must be satisfied by biospecimen resources as described in this section? | | | | | | |
| C.2.1.3 | If your biospecimen resource is involved with biospecimens that are used for in vitro diagnostic device studies, are you compliant with the FDA regulations covering informed consent in this area? | | | | | | |
| C.2.2 | Do you ensure that the research uses of biospecimens are consistent with the informed consent of the human research participant? | | | | | | |
| C.2.2.1 | Are your policies concerning the informed consent process, including when consent is sought from human research participants, transparent as described in this section? | | | | | | |
| C.2.2.2 | Do your investigators consider the beliefs and traditions of the community when planning a research study that will include the collection of biospecimens and consider the issues described in this section? | | | | | | |
| C.2.2.3 | Do you include the considerations described in this section, including ethical guidelines, logistical constraints and all stakeholders, in your timing for obtaining informed consent to use biospecimens for research purposes? | | | | | | |
| C.2.2.4 | Does your informed consent provide information about policies governing the retention of biospecimens, records pertaining to informed consent, and protections for the privacy of human research participants and the confidentiality of their data? | | | | | | |
| C.2.2.5 | Does your informed consent disclose whether biospecimens may at some point be anonymized and subsequently used for secondary research? | | | | | | |
| C.2.3.1 | Does your informed consent specify all five items in this section using straightforward language? | | | | | | |
| C.2.3.2 | Does your informed consent describe what types of data will be collected and how the data will be used and stored as described in this section? | | | | | | |
| C.2.3.2.a | Where applicable, does your informed consent state whether identifiable or coded information will be maintained in the biospecimen resource and if research results will be linked to other data about the human research participant as described in this section? | | | | | | |
| C.2.3.2.b | Does your informed consent clearly state if longitudinal data will be collected by accessing the participant's medical records? | | | | | | |
| C.2.3.2.c | If biospecimens and/or the data associated with or derived from biospecimens will be shared with other investigators, does your informed consent describe clearly the oversight mechanism(s) for such sharing? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| C.2.3.3 | Does your informed consent, if appropriate, include an option that allows human research participants to select whether they would be willing to be recontacted about the use of their biospecimen and/or data in future research studies? | | | | | | |
| C.2.3.4 | Does your informed consent state whether research participation would benefit or potentially negatively impact participants' families and communities, e.g., if there is a risk of stigmatization and/or discrimination based on research results? | | | | | | |
| C.2.3.5 | If applicable, does your informed consent include information about the types of genetic sequencing or analysis that will be conducted and the potential risks to the human research participant posed by such research as described in this section? | | | | | | |
| C.2.3.6.a | Does your informed consent address the use of biospecimens and/or data by private or for-profit entities and the possibility of research leading to future development of commercial products, as appropriate? | | | | | | |
| C.2.3.6.b | Does your informed consent describe whether human research participants, their families, or communities will receive any financial or nonfinancial benefits from the products, tests, or discoveries resulting from the research? | | | | | | |
| C.2.3.7 | Does your informed consent state whether individual or aggregate research results will be released to the human research participant, the participant's healthcare provider, or the participant's family and, if so, the mechanism for communicating such results? | | | | | | |
| C.2.3.8 | Does your biospecimen resource or institution easily share (e.g., brochure or web site) the general information about conflicts of interest, institutional policies for sharing samples with other investigators or companies, the financial implications of sharing, and any known or likely benefit to the institution or investigator? | | | | | | |
| C.2.3.9.a | If your informed consent includes a tiered system of consent, do you adhere to the human research participant's choices in order to ensure that his or her wishes are honored as described in this section? | | | | | | |
| C.2.3.9.b | If applicable, are the consent categories included in the tiered consent well defined and relatively constant over time? | | | | | | |
| C.2.3.9.c | Is your biospecimen resource's informatics system capable of tracking the levels of consent for each human research participant that are in place? | | | | | | |
| C.2.3.10 | If your biospecimen resource provides additional more-detailed information beyond that which is in your informed consent, do you have protocols in place to ensure that such materials are consistently offered to human research participants and that the content does not conflict with your informed consent as described in this section? | | | | | | |
| C.2.4.a | Does your informed consent highlight the human research participant's ability to discontinue participation in the research and describe what will take place should this occur? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| C.2.4.b | Have you developed procedures to track biospecimens and associated data for human research participants who discontinue participation in research? | | | | | | |
| C.2.4.c | Do you cease the collection of individually identifiable biospecimens or data and the use or testing of individually identifiable biospecimens already collected from that individual? | | | | | | |
| C.2.4.d | Do you withdraw from the biospecimen resource and cease from distributing for further research, any remaining identifiable biospecimens and associated clinical data from the human research participant? | | | | | | |
| C.2.4.e | When discontinuation of participation occurs, is any analysis of data that includes identifiable, private information generated from individually identifiable biospecimens obtained prior to the date of discontinuation of participation continued, provided that such analysis falls within the scope of the analysis described in the IRB-approved protocol? | | | | | | |
| C.2.4.f | Upon discontinuation of participation, are the identifiable specimens from that participant respectfully destroyed as described in this section? | | | | | | |
| C.2.4.g | When discontinuation of participation occurs, does your biospecimen resource custodian or director determine whether the human research participant intends to discontinue all types of participation or just certain types of participation? | | | | | | |
| C.2.4.h | Is your biospecimen resource sensitive to cultural issues and work with affected groups to develop mechanisms for the proper destruction of biospecimens or, as appropriate and practicable, the return of biospecimens to the individual or affected group (see Section C.2.2). | | | | | | |
| C.2.5.a | If you store identifiable biospecimens from children, have you carefully reviewed and understand the recommendations in C.2.5? | | | | | | |
| C.2.5.b | If you store identifiable biospecimens and/or identifiable data from children for future research use, have you considered the need for obtaining informed consent when the formerly pediatric human research participant reaches the legal age to consent for a research study? | | | | | | |
| C.3.1 | Do your privacy protocols reflect the previous and newly updated Federal regulations described in this section? | | | | | | |
| C.3.2.1.a | Does your biospecimen resource establish clear policies for protecting the confidentiality of identifiable information as described in this section? | | | | | | |
| C.3.2.1.b | Does your biospecimen resource currently utilize a “honest-broker”-guided procedure for sharing biospecimens and their associated data? | | | | | | |
| C.3.2.2 | If you obtain a certificate of confidentiality, do you explicitly state this in your informed consent as described in this section? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| C.3.2.3.a | Does your biospecimen resource document its policies for maintaining the privacy of human research participants and the confidentiality of associated clinical data, including descriptions of mechanisms for auditing effectiveness, enforcement measures, and required training for employees? | | | | | | |
| C.3.2.3.b | Is the level of security in your biospecimen resource appropriate to the type of biospecimen resource and the sensitivity of the data it houses? | | | | | | |
| C.3.2.4 | Does your biospecimen resource comply with all State and local statutes and regulations pertaining to privacy? | | | | | | |
| C.3.2.5 | Does your biospecimen resource use a system of data access with defined levels of access privileges for biospecimen resource staff in order to protect the confidentiality of human research participants' data as described in this section? | | | | | | |
| C.4.a | Has your biospecimen resource established guidelines for sample distribution and clinical data sharing consistent with ethical principles; governing statutes and regulations; and, if applicable, informed consent language as recommended in this section? | | | | | | |
| C.4.b | Has your biospecimen resource delineated when biospecimens and clinical data are narrowly or broadly accessible and what justifications should be provided in the access requests to the biospecimen resource as described in this section? | | | | | | |
| C.4.1 | Has your biospecimen resource, if applicable to the study design and biospecimen resource purpose, considered the specific access issues described in this section? | | | | | | |
| C.4.2 | Does your biospecimen resource have a scientifically sound and appropriate research plan as recommended in this section? | | | | | | |
| C.4.3 | Does your biospecimen resource have appropriate policies to ensure that researchers' access to biospecimens and associated clinical data is appropriate and in compliance with all applicable Federal and State privacy and human subjects regulations and statutes as well as the human research participant's informed consent as recommended in this section? | | | | | | |
| C.4.4.a | Does your biospecimen resource model emphasize accessibility to biospecimens and data and the sustainability of the biospecimen resource itself within a framework that maintains public trust as described in this section? | | | | | | |
| C.4.4.b | Does your biospecimen resource sustainability model include the potential loss of funding, e.g. do you have a legacy plan in place, as recommended in this section? | | | | | | |
| C.4.5.a | If your biospecimen resource makes public the existence of their biospecimens, e.g., resource's web site or other public sources, are the restrictions on accessibility to stored biospecimens indicated? | | | | | | |

| # | Questions: 122 Operations (A-B) & 74 ELSI (C) = 196 | % Completion | GAPS | Comment | FILLS | Comment | % Completion |
|---|---|---|---|---|---|---|---|
| C.4.5.b | Does your biospecimen resource encourage its investigators to indicate the source of the biospecimens when research data resulting from the use of your biospecimens are published? | | | | | | |
| C.5 | Does your biospecimen resource encourage and support the sharing of biospecimens in a timely manner, and to the extent possible, in a manner consistent with applicable NIH sharing policies as described in this section? | | | | | | |
| C.5.1 | Does your biospecimen resource's Material Transfer Agreement (MTA) include the desirable items indicated in this section? | | | | | | |
| C.5.2 | Does your biospecimen resource acknowledge that inventorship is generally not granted to those who solely curate the biospecimens, and that the status of "inventor" is determined by patent law and considered on a case-by-case basis by legal personnel? | | | | | | |
| C.5.3 | In general, does your biospecimen resource understand that it has no inherent rights to future IP of end-users, such as reach-through rights to inventions made by investigators using samples obtained from the biospecimen resource? | | | | | | |
| C.5.4 | Does your biospecimen resource understand that when IP resulting from biospecimen research is exclusively licensed, a research use license should be retained that allows nonprofit and Government research use and that ensures access to resources and data for research and educational purposes? | | | | | | |
| C.5.5.a | Does your biospecimen resource, through its MTAs or other appropriate documents and in compliance with the NIH Sharing Policy, require the release in a timely fashion of the research data sets and resources from the recipient investigators as described in this section? | | | | | | |
| C.5.5.b | Does your biospecimen resource, through its MTAs or other appropriate documents, share information that is identifiable or linked to a specific individual under an agreement with appropriate privacy safeguards and adherence to applicable legal requirement as described in this section? | | | | | | |
| C.6.1 | Does your biospecimen resource adhere to institutional and Public Health Service (PHS) regulations governing conflicts of interest (COIs) as described in this section? | | | | | | |
| C.6.2 | Does your biospecimen resource and/or institution identify, consider, manage, and disclose financial conflicts of interest (COI) as described in this section? | | | | | | |
| C.6.3 | Does your biospecimen resource and/or institution identify, consider, manage, and disclose nonfinancial conflicts of interest (COI) as described in this section? | | | | | | |

## Group(s) Involvement for Each Question

| | | Question Assigment | | | |
|---|---|---|---|---|---|
| # | Questions | BS | IT | ELSI | Other |
| A.1 | Do you understand the scope of the Best Practices as they apply to your facility? | | | | |
| B.1.1.1 | Have you defined and documented your organizational structure before your biospecimen resource planning and development? | | | | |
| B.1.1.2.a | Have you publicly displayed your current organizational chart within the biospecimen resource? | | | | |
| B.1.1.2.b | Do you discuss your current biospecimen resource organizational and institutional governance structures with every new employee? | | | | |
| B.1.2.1 | Have you defined the appropriate personnel and created the teams listed in this section that are appropriate to your institution? | | | | |
| B.1.2.2.a | Have you formed your Scientific Advisory Committee? | | | | |
| B.1.2.2.b | Have you formed your Tissue Utilization Committee? | | | | |
| B.1.2.3 | Have you included as stakeholders and consultants the associated institutional offices and adjunct committees as described in this section? | | | | |
| B.1.3.1.a | Have you defined and documented that your biospecimen resource's policies are in alignment with your biospecimen resource's mission, scope, and operational objectives? | | | | |
| B.1.3.1.b | Have you formally vetted and approved with documentation the policies defined in this section? | | | | |
| B.1.3.2.a | Has your biospecimen resource manager(s) familiarized her/himself with the Best Practices as described in this section? | | | | |
| B.1.3.2.b | Have your biospecimen resource staff and adjunct teams been oriented to the current Best Practices sufficiently so that they can follow them appropriately? | | | | |
| B.1.3.2.c | Have the Best Practices and current relevant standards been incorporated into your biospecimen resource policies, SOPs, and procedures using evidence-based practices when available? | | | | |
| B.1.3.3.a | Have you integrated your business planning into all aspects of operations, biospecimen resource management, and evaluation? | | | | |
| B.1.3.3.b | Have you established a documented annual business plan according to the recommendations in this section? | | | | |
| B.1.3.3.c | Does your business plan include a formal continuity plan that addresses all possible operational disruptions including disaster planning? | | | | |
| B.1.3.3.d | If your biospecimen resource functions as a service center, does your business plan address issues related to service and revenue generation? | | | | |
| B.1.4.a | Have you considered and documented the space requirements for the areas listed in this section? | | | | |
| B.1.4.b | In your biospecimen resource design and implementation, have you evaluated the options and opportunities for environmentally friendly infrastructure as described in this section? | | | | |
| B.1.5.1 | Have you considered the recommendations concerning equipment selection and maintenance in this section? | | | | |
| B.1.5.2 | Are you familiar with the purchasing and overall procurement process in your institution as described in this section? | | | | |
| B.1.5.3 | Have you developed a proactive project management plan with the sections described in this section? | | | | |
| B.1.5.4.a | Do you assess specimen utilization in a timely and efficient manner? | | | | |
| B.1.5.4.b | Do you document and track utilization in conjunction with the biospecimen resource inventory management system? | | | | |
| B.1.5.4.c | Do you share information about their biospecimens with the external (donor) community through a biospecimen management information system or other means? | | | | |
| B.1.6.1 | Are you prepared for and do you do self-audits to evaluate both the quality and the problem areas of your biospecimen resource, including monitoring end-user support for your clinical biobanking efforts? | | | | |
| B.1.6.2 | Do you do strategic and long-range planning including the setting of benchmarks? | | | | |
| B.1.6.3 | Do you quantify and document your performance including utilization review and the assessment of the continuing research needs of the biospecimen resource? | | | | |

| # | Questions | BS | IT | ELSI | Other |
|---|---|---|---|---|---|
| B.1.6.4 | Do you do a formal analysis of your biospecimen resource's scientific impact and document it? | | | | |
| B.2.1.1.1 | Do make an effort to collect and record the information about the patient's (donor's) physiological variables as recommended in this section? | | | | |
| B.2.1.1.2.a | Do you collect and record the methods used to remove, collect, and preserve your biospecimens in order to decrease the variability and improve the quality of your biospecimens as recommended in this section? | | | | |
| B.2.1.1.2.b | Do you have a plan in place, prior to the removal of a biospecimen, that allows the appropriate annotation of the biospecimen as recommended in this section? | | | | |
| B.2.1.1.3 | Do you optimize and document the handling and processing of your biospecimens to insure the highest quality of the biospecimens as recommended in this section? | | | | |
| B.2.1.2 | Do you minimize errors in assay reproducibility by implementing and documenting the recommendations made in this section? | | | | |
| B.2.2 | Are the biospecimens you collect appropriate and feasible for the clinical setting as well as being appropriate for the downstream applications anticipated for the biospecimens? | | | | |
| B.2.3 | Do you, when possible, characterize and document the reference range for the analyze of interest? | | | | |
| B.2.4.a | Are your standard operating procedures (SOPs) for analyte testing reproducible with standard reference materials using a range of anticipated assay values where possible? | | | | |
| B.2.4.b | When you analyze a specific biomolecule, do you perform and document the analyses that optimize the storage and handling conditions of the biospecimen(s) for that biomolecule? | | | | |
| B.2.5 | Do you incorporate into your research program, "proof of performance" tests as recommended in this section? | | | | |
| B.2.6.1 | Do you consistently apply, and document the consistent application, the SOPs used in preparing and storing biospecimens as described in this section? | | | | |
| B.2.6.2.a | Do you store frozen biospecimens in a stabilized state without unnecessary freeze-thaw cycles as described in this section? | | | | |
| B.2.6.2.b | Do you follow consistent and validated SOPs for thawing and re-freezing biospecimens? | | | | |
| B.2.6.3 | Are your biospecimen storage containers and labels appropriate for the biospecimens, and stable under the planned storage conditions, especially when using liquid nitrogen storage? | | | | |
| B.2.6.4 | Does each stored biospecimen have a unique identifier or combination of identifiers that are firmly attached to the storage container, clearly and legibly marked, and able to endure the storage conditions? | | | | |
| B.2.6.5 | Does your storage equipment have automated alarm systems that continuously monitor and warn biospecimen resource personnel when equipment failure occurs? | | | | |
| B.2.6.6 | Are your biospecimens stored in a secure location with limited access only by authorized personnel? | | | | |
| B.2.7 | Are your biospecimens retrieved from storage according to biospecimen resource SOPs that safeguard sample quality? | | | | |
| B.2.8.1.1 | Are your frozen biospecimens shipped according to biospecimen resource SOPs that safeguard sample quality, including a temperature measuring/recording device within the shipping container that indicates the minimum and/or maximum temperature that occurred during shipping? | | | | |
| B.2.8.1.2.a | Are your paraffin-embedded blocks shipped according to biospecimen resource SOPs that safeguard sample quality, including a temperature measuring/recording device within the shipping container that indicates the minimum and/or maximum temperature that occurred during shipping? | | | | |
| B.2.8.1.2.b | Are your fixed, but not paraffin-embedded, biospecimens shipped according to biospecimen resource SOPs that safeguard sample quality, including a temperature measuring/recording device within the shipping container that indicates the minimum and/or maximum temperature that occurred during shipping? | | | | |
| B.2.8.1.3.a | Do you place the number of biospecimens in a shipping container that are appropriate for the biospecimen and the container? | | | | |
| B.2.8.1.3.b | Do you perform a test shipment before shipping extremely valuable biospecimens as described in this section? | | | | |

| # | Questions | BS | IT | ELSI | Other |
|---|---|---|---|---|---|
| B.2.8.2.1 | When you plan the shipment of a biospecimen, do you create the required Material Transfer Agreement (MTA) and obtain the requisition from the biospecimen resource? | | | | |
| B.2.8.2.2.a | Do you notify the recipient before shipping to confirm that someone will be present to accept the package and properly store the biospecimen? | | | | |
| B.2.8.2.2.b | Does standardized paperwork (shipping manifest) accompany your shipments as well as an electronic version of the shipping manifest being sent to the recipient? | | | | |
| B.2.8.2.2.c | Upon receipt of your shipment, do the receiving personnel review the shipped biospecimen and manifest for discrepancies and document and resolve any discrepancies identified? | | | | |
| B.2.8.3.1 | When shipping biospecimens internationally, do you consult the ISBER Best Practices and International Air Transport Association (IATA) regulations and follow their recommendations and requirements? | | | | |
| B.2.8.3.2 | Do you consult the Occupational Safety and Health Administration (OSHA) regulations on toxic and hazardous substances (29 CFR 1910 Subpart Z) to determine whether a substance requires a biohazard label? | | | | |
| B.2.8.4 | Are your biospecimen resource personnel initially trained, and periodically retrained, on the regulations for shipping biospecimens internationally? | | | | |
| B.3.1 | Does your biospecimen resource carry out its functions within a quality management system (QMS) that contains formalized quality assurance/quality control (QA/QC) policies and written SOPs? | | | | |
| B.3.2.a | Does your biospecimen resource's quality management system implement and audit the staff proficiency following the recommendations in this section? | | | | |
| B.3.2.b | Does your biospecimen resource's quality management system implement and audit the facility infrastructure following the recommendations in this section? | | | | |
| B.3.2.c | Does your biospecimen resource's quality management system implement and audit the biospecimen control and documentation following the recommendations in this section? | | | | |
| B.3.2.d | Does your biospecimen resource's quality management system implement and audit the record keeping and document control following the recommendations in this section? | | | | |
| B.3.2.e | Does your biospecimen resource's quality management system implement and audit the scheduled and unscheduled internal audit programs and their policies following the recommendations in this section? | | | | |
| B.3.3.1 | Does your manual of standard operating procedures (SOPs) minimally include all twelve (12) areas recommended and described in this section? | | | | |
| B.3.3.2.a | Does the biospecimen resource director and/or the individual responsible for the QA/QC program review and approve all SOPs and associated process validation studies prior to implementation of the biospecimen resource? | | | | |
| B.3.3.2.b | Does the biospecimen resource director and/or the individual responsible for the QA/QC program evaluate the compliance and effectiveness of the QA/QC measures on a routine basis? | | | | |
| B.3.3.3.a | Does your biospecimen resource have a document control program and policies for governing, modifying, and/or revising SOPs? | | | | |
| B.3.3.3.b | Does the biospecimen resource director review all the SOPs at least every two (2) years and whenever significant modifications are made and document this review? | | | | |
| B.3.3.4.a | Are current copies of the SOPs manual stored in designated locations and available, either in hard copy or electronically, to the staff at all times? | | | | |
| B.3.3.4.b | Do the staff review new and revised SOPs and is each individual's review documented? | | | | |
| B.4.1.1 | Does your biospecimen resource use and monitor biohazard precautions/work practices similar to those used in clinical laboratories and clinical settings as described in this section? | | | | |
| B.4.1.2.a | Do you have clear policies regarding the inclusion or exclusion of high-risk biospecimens as described in this section? | | | | |
| B.4.1.2.b | Have your biospecimen resource personnel been trained, and the individual training documented, to perform biospecimen risk assessments and determine the appropriate levels of containment? | | | | |
| B.4.1.3 | Have you established policies consistent with CDC's "Select Agents and Toxins" regulations as described in this section? | | | | |

| # | Questions | BS | IT | ELSI | Other |
|---|---|---|---|---|---|
| B.4.2.1 | Have you developed or are developing your overall biohazard safety and training program and were/are the governmental and accrediting agencies requirements incorporated as described in this section? | | | | |
| B.4.2.2 | Do you frequently identify biospecimen resource activities that may have safety issues and implement suitable controls? | | | | |
| B.4.2.3 | Is your biohazard safety and training program reviewed on a periodic basis including review of any relied upon updated governmental and/or accrediting biosafety guidelines? | | | | |
| B.4.2.4 | Do you document the biohazard precautions/work practice training and competence on an individual basis? | | | | |
| B.4.2.5 | Do you have a SOP regarding the documentation of, and the treatment of, all incidents within your biospecimen resource where personnel are exposed to biohazards and/or are potentially infected? | | | | |
| B.4.3 | Does your biospecimen resource follow strict general safety regulations and procedures regarding chemical, electrical, fire, physical, and radiological safety? | | | | |
| B.5.1.1 | Do your data collection activities conform to FDA requirements, if and where applicable, so that the data may be cited and/or used in Investigational New Drug and Investigational Device Exemption applications as described in this section? | | | | |
| B.5.2.1 | When appropriate, do you collect relevant clinical data associated with a biospecimen in accordance with relevant human subject and privacy regulations? | | | | |
| B.5.2.2 | Do you employ a uniform, nonredundant vocabulary for clinical data as described in this section? | | | | |
| B.5.2.3 | Does your biospecimen resource comply with applicable privacy statutes and regulations and human subjects protection regulations governing the acquisition of biospecimens and associated clinical data as described in this section? | | | | |
| B.5.2.4 | Do you track researcher's requests for specimens with specific clinical data to guide the refinement of clinical data collection as described in this section? | | | | |
| B.5.3.1 | When the study requirements dictate, do you collect and store longitudinal data following applicable informed consent and authorization requirements as described in this section? | | | | |
| B.5.3.2 | Do you use a Minimal Clinical Data Set for linking certain clinical data to a biospecimen such as demographic data, lifestyle factors, environmental and occupational exposures, cancer history, structured pathology data, additional diagnostic studies, information on initial staging procedure, treatment data, and any other data relevant to tracking a research participant's clinical outcome as described in this section? | | | | |
| B.5.3.3 | If you develop databases for longitudinal studies, is the coded data associated with a biospecimen securely linked to the donor so that longitudinal data can be added to the record if permitted by law and by the donor's consent/authorization documents? | | | | |
| B.5.3.4 | Are your policies and protocols optimized to facilitate access to uniform longitudinal data as appropriate, while protecting the donor's privacy and confidentiality? | | | | |
| B.5.3.5 | Do you ensure that dedicated and trained personnel curate your longitudinal clinical data with validation of the collection process and QA/QC? | | | | |
| B.5.4.1 | Does your informatics system track all aspects of biospecimen collection, processing, and distribution to support high-quality annotation of the biospecimen, its characteristics, and other associated data (see Section B.6 for details)? | | | | |
| B.6 | Have you read this section and understand how data management, inventory control, and biospecimen tracking need to be implemented in your biospecimen resource as described in this section? | | | | |
| B.6.1.1 | Is your biospecimen resource informatics system focused on recording data types as described in Section B.5., including the inventory functions listed in this section? | | | | |
| B.6.1.2 | Does your biospecimen resource informatics system have the capability of linking labels on the physical biospecimen container to other information regarding that biospecimen in the system? | | | | |
| B.6.1.3 | Does your biospecimen resource informatics system track clinical data associated with a biospecimen and/or link biospecimen data with external sources of clinical data, where applicable? | | | | |
| B.6.1.4 | Does your biospecimen resource informatics system monitor and report on biospecimen quality in terms of the scientific best practices defined in Section B.2.? | | | | |

| # | Questions | BS | IT | ELSI | Other |
|---|---|---|---|---|---|
| B.6.1.5 | Does your biospecimen resource informatics system provide vital system statistics and audit logs of all access to protected health information in the database? | | | | |
| B.6.2.1 | Does your informatics system record the origin of each physical part created by extraction, division into aliquots, or other physical division of a biospecimen? | | | | |
| B.6.2.2 | Does each biospecimen have a globally unique identifier or combination of identifiers assigned (number or barcode [preferable]) as described in this section? | | | | |
| B.6.2.3 | Does your biospecimen resource informatics system track biospecimen processing, storage, distribution and return of biospecimens and their derived information from clients and associate them with the appropriate information derived from the original biospecimen? | | | | |
| B.6.2.4 | Does your biospecimen resource informatics system update the database each time a biospecimen or sample is moved within or out of the biospecimen resource by tracking its location? | | | | |
| B.6.3.1 | Does your biospecimen resource informatics system have the interoperability to enable integration with local and with other cross-site systems? | | | | |
| B.6.3.2 | Does your biospecimen resource informatics system have the interoperability to enable integration with other clinical data systems such as the anatomic and clinical laboratory information system(s), and cancer registries? | | | | |
| B.6.3.3 | Does your biospecimen resource informatics system support a minimum set of common queries that can be submitted to all systems using common data elements (CDEs)? | | | | |
| B.6.3.4 | Is your biospecimen resource informatics system caBIG compatible? | | | | |
| B.6.3.5 | Can your biospecimen resource informatics system utilize data elements from a common metadata repository, such as the Cancer Data Standards Repository? | | | | |
| B.6.3.6 | Can your biospecimen resource informatics management system share appropriate, deidentified biospecimen data to users at remote locations for multiple purposes including satisfying reporting and regulatory requirements as well as searching for potential biospecimens for a proposed scientific study? | | | | |
| B.6.4.1 | Is your biospecimen resource informatics system based on “use cases” and other techniques that capture needs for managing biospecimen resources and implemented via appropriate SOPs? | | | | |
| B.6.4.2 | Does your biospecimen resource informatics system use software and system development methodology for initial development and subsequent revisions ? | | | | |
| B.6.4.3 | Does your biospecimen resource software and system engineering organizations meet at least Capability Maturity Model Integration [CMMI] Level 3? | | | | |
| B.6.5.1 | Have you identified the minimum set of requirements for software needs and storage needs to address current and estimated future needs? | | | | |
| B.6.5.2 | Have you used the criteria you defined in Section B.6.5.1 to judge mature open-source and commercially available systems as described in this section? | | | | |
| B.6.6.1 | Does your biospecimen resource informatics system have an operational infrastructure to support operation 24 hours a day, 7 days a week? | | | | |
| B.6.6.2 | Does your biospecimen resource informatics system have processes in place to cope with system downtimes and disaster recovery? | | | | |
| B.6.6.3 | Is your biospecimen resource informatics system periodically evaluated to ensure that the system is fulfilling the criteria advised in the Best Practices and the latest needs of the Biospecimen resource? | | | | |
| B.6.6.4 | Does your biospecimen resource informatics system have the capability to routinely monitor and validate the accuracy of the tools you use to extract structured information from free-text data, such as surgical pathology reports? | | | | |
| B.6.6.5 | Are all of your biospecimen resource informatics system databases at an individual institution in a secure site and monitored by the institution as described in this section? | | | | |
| B.6.7.1.a | Does your biospecimen resource informatics system meet relevant State and Federal requirements that encourage the use of electronic signature where appropriate? | | | | |
| B.6.7.1.b | Does your biospecimen resource informatics system meet relevant State and Federal requirements that encourage the use of information technology accessibility standards for handicapped persons where appropriate? | | | | |

| # | Questions | BS | IT | ELSI | Other |
|---|---|---|---|---|---|
| B.6.7.2 | Do you refer to the National Institute of Standards and Technology Special Publication 800-30 “Risk Management Guide for Information Technology Systems” to determine the appropriate level of security for your informatics systems? | | | | |
| C.1 | Does your biosepcimen resource understand the scope of the Ethical, Legal, and Policy section of the Best Practices: Principles of Responsible Custodianship as described in this section? | | | | |
| C.1.1 | Does your biospecimen resource address formal and continuing responsibility for custodianship of collected biospecimens and associated data as part of their protocols, including the issues described in this secction that should be addressed in the governance plan? | | | | |
| C.1.2.a | Does your biospecimen resource have a legacy or contingency plan as part of the overall governance plan as described in this section? | | | | |
| C.1.2.b | Does your biospecimen resource’s legacy or contingency plan address the handling and disposition of biospecimens and associated data at one or more of the points described in this section? | | | | |
| C.1.3.a | Has your biospecimen resource established and documented transparent policies governing the retention of biospecimens and data? | | | | |
| C.1.3.b | Do your biospecimen resource’s usage agreements, such as MTAs, specify the retention policies of the recipient investigator and other considerations related to specimen retention as escribed in this section? | | | | |
| C.1.4 | Does your biospecimen resource, as a responsible custodian, manage existing or potential conflict of interests (COIs) and adhere to regulations regarding COIs at 42 CFR Part 50 Subpart F as described in this section as well as other applicable regulations and policies. (Also see Section C.6, Conflicts of Interest.)? | | | | |
| C.1.5.b | Does your biospecimen resource implement transparent policies for maintaining the confidentiality and security of the biospecimens and associated clinical data, if applicable, as described in this section? | | | | |
| C.1.6.a | Does your biospecimen resource, where practicable, share the general information described in this section with human research participants via their web site or alternate mechanism? | | | | |
| C.1.6.b | Does your biospecimen resource include the information and/or the corresponding Web link described in Section C.1.6.a. above, in the informed consent supplementary material; e.g., a brochure? | | | | |
| C.1.7 | Does your biospecimen resource make public (e.g., on a web site) a summary of its governance plan and/or an accompanying graphic of its organization? | | | | |
| C.2 | Do you understand the scope of the informed consent for biospecimen donation as described in this section? | | | | |
| C.2.1.1 | Do you track whether appropriate informed consent is present (if applicable) or the reason why informed consent is not necessary? | | | | |
| C.2.1.2 | Have you satisfied the Office for Human Research Protections (OHRP) guidance on the regulatory requirements that must be satisfied by biospecimen resources as described in this section? | | | | |
| C.2.1.3 | If your biospecimen resource is involved with biospecimens that are used for in vitro diagnostic device studies, are you compliant with the FDA regulations covering informed consent in this area? | | | | |
| C.2.2 | Do you ensure that the research uses of biospecimens are consistent with the informed consent of the human research participant? | | | | |
| C.2.2.1 | Are your policies concerning the informed consent process, including when consent is sought from human research participants, transparent as described in this section? | | | | |
| C.2.2.2 | Do your investigators consider the beliefs and traditions of the community when planning a research study that will include the collection of biospecimens and consider the issues described in this section? | | | | |
| C.2.2.3 | Do you include the considerations described in this section, including ethical guidelines, logistical constraints and all stakeholders, in your timing for obtaining informed consent to use biospecimens for research purposes? | | | | |
| C.2.2.4 | Does your informed consent provide information about policies governing the retention of biospecimens, records pertaining to informed consent, and protections for the privacy of human research participants and the confidentiality of their data? | | | | |

| # | Questions | BS | IT | ELSI | Other |
|---|---|---|---|---|---|
| C.2.2.5 | Does your informed consent disclose whether biospecimens may at some point be anonymized and subsequently used for secondary research? | | | | |
| C.2.3.1 | Does your informed consent specify all five items in this section using straightforward language? | | | | |
| C.2.3.2 | Does your informed consent describe what types of data will be collected and how the data will be used and stored as described in this section? | | | | |
| C.2.3.2.a | Where applicable, does your informed consent state whether identifiable or coded information will be maintained in the biospecimen resource and if research results will be linked to other data about the human research participant as described in this section? | | | | |
| C.2.3.2.b | Does your informed consent clearly state if longitudinal data will be collected by accessing the participant's medical records? | | | | |
| C.2.3.2.c | If biospecimens and/or the data associated with or derived from biospecimens will be shared with other investigators, does your informed consent describe clearly the oversight mechanism(s) for such sharing? | | | | |
| C.2.3.3 | Does your informed consent, if appropriate, include an option that allows human research participants to select whether they would be willing to be recontacted about the use of their biospecimen and/or data in future research studies? | | | | |
| C.2.3.4 | Does your informed consent state whether research participation would benefit or potentially negatively impact participants' families and communities, e.g., if there is a risk of stigmatization and/or discrimination based on research results? | | | | |
| C.2.3.5 | If applicable, does your informed consent include information about the types of genetic sequencing or analysis that will be conducted and the potential risks to the human research participant posed by such research as described in this section? | | | | |
| C.2.3.6.a | Does your informed consent address the use of biospecimens and/or data by private or for-profit entities and the possibility of research leading to future development of commercial products, as appropriate? | | | | |
| C.2.3.6.b | Does your informed consent describe whether human research participants, their families, or communities will receive any financial or nonfinancial benefits from the products, tests, or discoveries resulting from the research? | | | | |
| C.2.3.7 | Does your informed consent state whether individual or aggregate research results will be released to the human research participant, the participant's healthcare provider, or the participant's family and, if so, the mechanism for communicating such results? | | | | |
| C.2.3.8 | Does your biospecimen resource or institution easily share (e.g., brochure or web site) the general information about conflicts of interest, institutional policies for sharing samples with other investigators or companies, the financial implications of sharing, and any known or likely benefit to the institution or investigator? | | | | |
| C.2.3.9.a | If your informed consent includes a tiered system of consent, do you adhere to the human research participant's choices in order to ensure that his or her wishes are honored as described in this section? | | | | |
| C.2.3.9.b | If applicable, are the consent categories included in the tiered consent well defined and relatively constant over time? | | | | |
| C.2.3.9.c | Is your biospecimen resource's informatics system capable of tracking the levels of consent for each human research participant that are in place? | | | | |
| C.2.3.10 | If your biospecimen resource provides additional more-detailed information beyond that which is in your informed consent, do you have protocols in place to ensure that such materials are consistently offered to human research participants and that the content does not conflict with your informed consent as described in this section? | | | | |
| C.2.4.a | Does your informed consent highlight the human research participant's ability to discontinue participation in the research and describe what will take place should this occur? | | | | |
| C.2.4.b | Have you developed procedures to track biospecimens and associated data for human research participants who discontinue participation in research? | | | | |
| C.2.4.c | Do you cease the collection of individually identifiable biospecimens or data and the use or testing of individually identifiable biospecimens already collected from that individual? | | | | |
| C.2.4.d | Do you withdraw from the biospecimen resource and cease from distributing for further research, any remaining identifiable biospecimens and associated clinical data from the human research participant? | | | | |

| # | Questions | BS | IT | ELSI | Other |
|---|---|---|---|---|---|
| C.2.4.e | When discontinuation of participation occurs, is any analysis of data that includes identifiable, private information generated from individually identifiable biospecimens obtained prior to the date of discontinuation of participation continued, provided that such analysis falls within the scope of the analysis described in the IRB-approved protocol? | | | | |
| C.2.4.f | Upon discontinuation of participation, are the identifiable specimens from that participant respectfully destroyed as described in this section? | | | | |
| C.2.4.g | When discontinuation of participation occurs, does your biospecimen resource custodian or director determine whether the human research participant intends to discontinue all types of participation or just certain types of participation? | | | | |
| C.2.4.h | Is your biospecimen resource sensitive to cultural issues and work with affected groups to develop mechanisms for the proper destruction of biospecimens or, as appropriate and practicable, the return of biospecimens to the individual or affected group (see Section C.2.2). | | | | |
| C.2.5.a | If you store identifiable biospecimens from children, have you carefully reviewed and understand the recommendations in C.2.5? | | | | |
| C.2.5.b | If you store identifiable biospecimens and/or identifiable data from children for future research use, have you considered the need for obtaining informed consent when the formerly pediatric human research participant reaches the legal age to consent for a research study? | | | | |
| C.3.1 | Do your privacy protocols reflect the previous and newly updated Federal regulations described in this section? | | | | |
| C.3.2.1.a | Does your biospecimen resource establish clear policies for protecting the confidentiality of identifiable information as described in this section? | | | | |
| C.3.2.1.b | Does your biospecimen resource currently utilize a “honest-broker”-guided procedure for sharing biospecimens and their associated data? | | | | |
| C.3.2.2 | If you obtain a certificate of confidentiality, do you explicitly state this in your informed consent as described in this section? | | | | |
| C.3.2.3.a | Does your biospecimen resource document its policies for maintaining the privacy of human research participants and the confidentiality of associated clinical data, including descriptions of mechanisms for auditing effectiveness, enforcement measures, and required training for employees? | | | | |
| C.3.2.3.b | Is the level of security in your biospecimen resource appropriate to the type of biospecimen resource and the sensitivity of the data it houses? | | | | |
| C.3.2.4 | Does your biospecimen resource comply with all State and local statutes and regulations pertaining to privacy? | | | | |
| C.3.2.5 | Does your biospecimen resource use a system of data access with defined levels of access privileges for biospecimen resource staff in order to protect the confidentiality of human research participants’ data as described in this section? | | | | |
| C.4.a | Has your biospecimen resource established guidelines for sample distribution and clinical data sharing consistent with ethical principles; governing statutes and regulations; and, if applicable, informed consent language as recommended in this section? | | | | |
| C.4.b | Has your biospecimen resource delineated when biospecimens and clinical data are narrowly or broadly accessible and what justifications should be provided in the access requests to the biospecimen resource as described in this section? | | | | |
| C.4.1 | Has your biospecimen resource, if applicable to the study design and biospecimen resource purpose, considered the specific access issues described in this section? | | | | |
| C.4.2 | Does your biospecimen resource have a scientifically sound and appropriate research plan as recommended in this section? | | | | |
| C.4.3 | Does your biospecimen resource have appropriate policies to ensure that researchers’ access to biospecimens and associated clinical data is appropriate and in compliance with all applicable Federal and State privacy and human subjects regulations and statutes as well as the human research participant’s informed consent as recommended in this section? | | | | |
| C.4.4.a | Does your biospecimen resource model emphasize accessibility to biospecimens and data and the sustainability of the biospecimen resource itself within a framework that maintains public trust as described in this section? | | | | |

| # | Questions | BS | IT | ELSI | Other |
|---|---|---|---|---|---|
| C.4.4.b | Does your biospecimen resource sustainability model include the potential loss of funding, e.g. do you have a legacy plan in place, as recommended in this section? | | | | |
| C.4.5.a | If your biospecimen resource makes public the existence of their biospecimens, e.g., resource's web site or other public sources, are the restrictions on accessibility to stored biospecimens indicated? | | | | |
| C.4.5.b | Does your biospecimen resource encourage its investigators to indicate the source of the biospecimens when research data resulting from the use of your biospecimens are published? | | | | |
| C.5 | Does your biospecimen resource encourage and support the sharing of biospecimens in a timely manner, and to the extent possible, in a manner consistent with applicable NIH sharing policies as described in this section? | | | | |
| C.5.1 | Does your biospecimen resource's Material Transfer Agreement (MTA) include the desirable items indicated in this section? | | | | |
| C.5.2 | Does your biospecimen resource acknowledge that inventorship is generally not granted to those who solely curate the biospecimens, and that the status of "inventor" is determined by patent law and considered on a case-by-case basis by legal personnel? | | | | |
| C.5.3 | In general, does your biospecimen resource understand that it has no inherent rights to future IP of end-users, such as reach-through rights to inventions made by investigators using samples obtained from the biospecimen resource? | | | | |
| C.5.4 | Does your biospecimen resource understand that when IP resulting from biospecimen research is exclusively licensed, a research use license should be retained that allows nonprofit and Government research use and that ensures access to resources and data for research and educational purposes? | | | | |
| C.5.5.a | Does your biospecimen resource, through its MTAs or other appropriate documents and in compliance with the NIH Sharing Policy, require the release in a timely fashion of the research data sets and resources from the recipient investigators as described in this section? | | | | |
| C.5.5.b | Does your biospecimen resource, through its MTAs or other appropriate documents, share information that is identifiable or linked to a specific individual under an agreement with appropriate privacy safeguards and adherence to applicable legal requirement as described in this section? | | | | |
| C.6.1 | Does your biospecimen resource adhere to institutional and Public Health Service (PHS) regulations governing conflicts of interest (COIs) as described in this section? | | | | |
| C.6.2 | Does your biospecimen resource and/or institution identify, consider, manage, and disclose financial conflicts of interest (COI) as described in this section? | | | | |
| C.6.3 | Does your biospecimen resource and/or institution identify, consider, manage, and disclose nonfinancial conflicts of interest (COI) as described in this section? | | | | |

# NCI COMMUNITY CANCER CENTERS PROGRAM

# 2007–2014

Leidos Biomedical Research, Inc.